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INTELLECTUAL PROPERTY AND THE GLOBAL CRISIS OF NON-COMMUNICABLE DISEASE

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This Article reconsiders the drugs-for-the-developing world debate that has taken place in the shadow of free trade liberalization. For the last twenty years, this debate has centered on a supposedly zero-sum conflict between access to drugs for residents of the "third world" and incentives for pharmaceutical multinationals to invest in research and development. Underlying this debate is the assumption that the developing-world health crisis involves primarily a crisis of infectious disease. Because drugs for such ailments lack developed world markets, it is easy to imagine that robust pharmaceutical patents are globally necessary if the poor are to obtain any drugs at all. Global public health reality, however, is quite different. Mortality and morbidity in developing countries are increasingly attributable to those same non-communicable diseases ("NCDs") that plague developed countries. Drugs for such conditions already have highly profitable developed world markets. Therefore, making developing-world populations pay patent-inflated prices encourages rent-seeking by multinationals rather than incentivization. While little noticed in the developed world, the importance of the NCD crisis has not been lost on developing world actors. This Article is the first to document a recent worldwide trend of developing-world courts and administrative agencies breaking with strict patent rights for NCD drugs. It argues that attentive policy makers can seize the opportunity provided by the crisis that developed world populism is creating for liberalizing globalization. If renegotiating free trade is back on the agenda, they need only look to what developing countries have already been doing, at least in the realm of intellectual property rights.

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I. INTRODUCTION

The populist upsurge of 2016 in the Atlantic world has brought many surprises; the election of Donald Trump in the United States and Britain's vote to leave the European Union being two of the most visible. While the outcome of these developments is yet to be fully determined, it is obviously difficult to see them other than as signs of a crisis in the prevailing world order. As is the case with any crisis, however, its indicia may foretell unpredictable opportunities as well. Of course, the Trump administration's immediate move to withdraw from the Trans-Pacific Partnership (TPP)[1]—international economic law's most recent hope for advancing globalization—may foretell a slight adjustment rather than any real reversal to the liberalizing commitment. At the same time, whatever its source, greater attention to the possible inequities of the global trading system still portends more of a chance that the terms of free trade liberalization will be reconsidered than has been the case at any previous time in recent memory.

Although many questions remain unanswered—including whether the Trump administration will end up simply pursuing a bilateral, rather than multilateral, version of the free trade status quo—some things are for certain. Among these certainties is that growing populist scrutiny of liberalizing free trade's achievements has now dovetailed with a mounting concern in places like the U.S. and Britain over out-of-control pharmaceutical costs, a problem that had once seemed to plague health systems in the developing world alone. In the U.S., for example, consumer outrage reached its most fevered pitch amidst the dramatic 600% price increase in Mylan, N.V.'s EpiPen epinephrine auto-injector in the late summer of 2016.[2] At the very same time, on the other side of the Atlantic, Britain's National Health Service (NHS) turned down Roche

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[1] For the origins of the TPP, see Meredith Kolsky Lewis, *Expanding the P-4 Trade Agreement into a Broader Trans-Pacific Partnership: Implications, Risks and Opportunities*, 4 ASIAN J. WTO & INT'L HEALTH L. & POL'Y 401 (2009).

[2] The controversy elicited a U.S. Department of Justice investigation of Mylan N.V., which was settled in August, 2017, for $465 million. *See* Nate Raymond, *Mylan, U.S. Finalize $465 Million EpiPen Settlement*, REUTERS (Aug. 17, 2017), https://www.reuters.com/article/us-mylan-epipen/mylan-u-s-finalize-465-million-epipen-settlement-idUSKCN1AX1RW.

Pharmaceutical's blockbuster breast cancer therapy Kadcyla for the second time in two years.[3] Running more than $100,000 per patient per year, the NHS declared the patent-protected drug simply too expensive,[4] especially given Roche's own cost of just over $100.[5]

Of course, for those versed in the last twenty years of the debate pitting the need for essential medicines for the world's poor against the intellectual property rights ("IP" or "IPRs") of pharmaceutical multinationals, it may seem naïve to imagine that the actual cost of Kadcyla is so little. After all, such debate commenced from the clear support of our era's foundational free trade agreement, the World Trade Organization ("WTO"), for the upward harmonization of national IPR standards.[6] The WTO's annex on Trade Related Aspects of Intellectual Property ("TRIPS")[7] has thus supported strong patent rights in the name of enabling firms like those in the pharmaceutical sector to recoup the hundreds of millions, if not billions, of dollars they claim to spend on developing new medicines.[8] Yet there remains an important difference between the

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[3] Kadcyla is the brand name for trastuzumab emtansine. As discussed in Part V, Roche has been involved in conflict over a patent on the unadorned form of trastuzumab, or Herceptin, in India.

[4] John Ainger, *Make Drugmakers Pay: England's Strategy for Cancer Medicines*, BLOOMBERG NEWS (July 28, 2016), https://www.bloomberg.com/news/articles/2016-07-28/cancer-drugs-fund-revamp-means-drugmakers-shoulder-overspending.

[5] Lois Rogers, *Sickening Rip Off*, THE DAILY MAIL (Nov. 16, 2015), http://www.dailymail.co.uk/health/article-3321121/Sickening-rip-Smaller-matchstick-year-s-dose-life-extending-blood-cancer-drug-NHS-pays-115-000-costs-just-100-make.html.

[6] *See* Frederick M Abbott, *The Enduring Enigma of TRIPS: A Challenge for the World Economic System*, 1 J. INT'L ECON. L. 497, 499 (1998).

[7] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

[8] The most widely cited (and criticized) figures come from Tufts Center for the Study of Drug Development. The Center's 2003 study reported the $800 million number (or $1 billion in 2013 dollars). That figure became $2.6 billion by the time the Center undertook its 2013 updated study. Although the 2014 study is inaccessible online, for the official summary, see Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20 (2016). For concern about the study, see Aaron E. Carroll, *$2.6 Billion to Develop a Drug? New Estimate*

intensifying concern about drug costs in the "first world" and the standing debate about access to medicines in the "third world." Even without the proprietary information required for a true accounting, the ordinary inhabitant of the developed world would still likely balk at such figures. Instead, inhabitants of the developed world would feel only vaguely trapped by dire warnings of a greater number of their countrymen left to die or suffer in a counterfactual world without any drugs at all, absent $99,000-plus markups.

Makes Questionable Assumptions, N.Y. TIMES: THE UPSHOT (Nov. 18, 2014), https://www.nytimes.com/2014/11/19/upshot/calculating-the-real-costs-of-developing-a-new-drug.html?_r=1. *See also* MERRILL GOOZNER, THE $800 MILLION PILL: THE TRUTH BEHIND THE COST OF NEW DRUGS (2004). More recently, dueling (and very different) estimates of R&D costs have emerged. *See* Joseph A. DiMasi, H.G. Grabowski & R.W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20 (2016) (sampling 106 randomly selected drugs from ten large pharmaceutical firms to arrive at a total pre-approval cost estimate of $2.558 billion in 2013); Vinay Prasad & Sham Mailankody, *Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval*, JAMA: INTERNAL MED. (Sep. 11, 2017), https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2653012 (using the Securities and Exchange Commission's reports for investors to arrive at total R&D figures for cancer drugs put out by ten companies in the period from 2007 to 2015 and finding a median cost of $648 million). For a discussion of limitations of DiMasi's paper and problems accessing its underlying data, see James Love, *Perspectives on Cancer Drug Development Costs in JAMA,* HARV. L. BILL OF HEALTH (Sept. 13, 2017), http://blogs.harvard.edu/billofhealth/2017/09/13/perspectives-on-cancer-drug-development-costs-in-jama/. As Love notes, these various controversies about R&D costs are entirely aside from whether R&D outlays are even relevant to determining pharmaceutical prices, which a great deal of evidence suggests they are not, given that companies instead charge what they think the market can bear. As he notes, the back and forth also fails to give much attention to the misleading character of industry averages of R&D costs given how wide variation for different drugs tends to be. Love gives the example of Spinraza, a drug that runs up to $750,000 for one year's course of treatment. He cites a study by Knowledge Ecology International, developed largely through government grants, calculating its risk-adjusted R&D costs at $40 million. *Id.* For the latter calculation, see Andrew Goldman, *Written Submission in Support of HB 666*, KNOWLEDGE ECOLOGY INT'L (Mar. 16, 2017), https://www.keionline.org/sites/default/files/KEI-Goldman-HB666-transparency-16March2017-Maryland.pdf.

The overall aim of this Article is to ask why such warnings seem much more compelling when thinking about illness in the developing world. The article's answer is that such warnings have long taken on a surface plausibility for low and middle-income countries[9] due to highly restricted assumptions about the diseases faced by these countries' inhabitants. The public health crisis in the developing world has thus been construed largely, if not entirely, in terms of communicable or infectious diseases (like tuberculosis and malaria).[10] From its very outset, the drugs-for-the-developing world debate involved both critics and supporters of TRIPS alike focused mainly on drugs for diseases that had no effective markets in high-income countries (except for the unique case of HIV/AIDS).[11] As a result, it has always implicitly drawn on fact scenarios that make choosing between competing normative considerations about ensuring access to drugs and incentivizing their production to seem like a zero-sum dilemma.

In coming to my own normative argument, this Article highlights a shift now taking place in the nature of health crisis in the developing world. This involves *non-communicable diseases* (NCDs) increasingly replacing infectious diseases as the highest cause of morbidity and mortality in low and middle-income countries. This shift is crucial because NCDs entail drugs that *do* have markets in the developed world and highly profitable markets by the multinational pharmaceutical sector's own account.[12]

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[9] For simplicity's sake, the term "low- and middle-income countries" is used equivalently with "developing countries/world." For a proper description of these categories, see *infra* notes 60–61.

[10] I will use the terms communicable disease and infectious disease interchangeably, though they have slightly different definitions. According to the World Health Organization (WHO), communicable diseases are generally those ailments that can be transmitted from person-to-person, while "[i]nfectious diseases are caused by pathogenic microorganisms, such as bacteria, viruses, parasites or fungi" and "can be spread, directly or indirectly, from one person to another." *Health Topics: Infectious Diseases*, WORLD HEALTH ORG., http://www.who.int/topics/infectious_diseases/en/ (last visited Feb. 11, 2017).

[11] For simplicity's sake, the term "high-income countries" is used equivalently with "developed countries/world." For a proper description of this category, see *infra* note 61.

[12] For a more detailed discussion of these points, see *infra* Sections IV and V.

Developed world markets can amortize real research and development (R&D) costs. NCD drugs make it strikingly clear that, rather than being necessary to incentivize away from a world without medicines, pushing for patent-inflated pricing through the upward harmonization of a national IP regime design in developing countries is likely a form of rent-seeking.

Our existing debate has obscured this reality through an ostensibly context-free mode of "in theory" argument (even as it has implicitly equated the problem of "third world" health with the impact of non-remunerative infectious disease). In the process, it has created the misleading sense that the normative aims of access and incentivization entail an imminent tradeoff. If we instead consider the growing NCD crisis the developing world is facing, we begin to see how legal and administrative conflicts in low and middle-income countries have been shifting in recent years. Accordingly, this Article is the first of its kind to unveil how low and middle-income countries have increasingly moved toward contesting strict patent rights on drugs for conditions like cancer, cardiovascular disease, and assorted chronic ailments. As I contend, this shift amounts to a wave of strategic action recalibrating focus onto those fact scenarios that are *the least likely* to trigger an imminent zero-sum tradeoff between access and incentivization.

Little-noticed by academics and policy makers in the developed world, both of these shifts—in the profile of disease burden *and* the pattern of legal/administrative conflict in the developing world—have been afoot since 2010. Preceding the current populist upsurge for renegotiating the terms of free trade in places like the U.S. and Britain by more than a half-decade, these shifts furnish a ready template for law and policy makers to draw on when addressing the more specific questions they will now face about rewriting the rules of national IP regime design. Therefore, making sense of the shifting contexts that inform questions about pharmaceutical access versus incentivization in the way is of vital importance. This, moreover, is not simply with respect to the inhabitants of the developing world, but also to those outside of its borders—especially in the United States. If bipartisan action against out-of-control drug prices in the U.S. does materialize, opposition based on the supposed imminence of the access-incentivization dilemma will grow much louder.

To pursue its descriptive and normative goals, this Article proceeds in five parts. Part II previews the shifting landscape of conflict over IPRs and access to medicines. A landmark 2013 decision is briefly discussed in which the Indian Supreme Court rejected the Swiss pharmaceutical giant Novartis' patent application for a prominent anti-cancer drug due to its lack of inventiveness. One of a growing number, the case is used as a launching point for the more telescopic perspective this Article provides. Part III turns to a brief historical account of how the remote theoretical tension between pharmaceutical access and incentivization became an urgent conundrum after the founding of the WTO. This tension grew in tandem with the rise of a debate on drugs-for-the-developing world rooted in concerns about TRIPS' impact on the well-being of the world's poor. Part IV examines the picture of the public health crisis in the developing world as an over-looked crisis of infectious disease; it also emphasizes the changing nature of illness in low and middle-income countries due to the (ongoing) explosion of health and economic loss from NCDs. Part V contemplates how, despite the ambiguities of normative IP theory and the place of patents in any country's innovation system, the access-incentivization dilemma has nonetheless been further mapped onto a dichotomy between short-term ethics and the long-term rationality of economics. This section will describe how assuming a factual backdrop of infectious disease effectively buttressed the prevailing status quo in favor of strict approaches to patent rights and the upward harmonization of national IP regime design.[13] Finally, Part VI documents the burgeoning examples, since 2010, of courts and administrative agencies developing countries engaging in new forms of strategic action to break with strict patent rights in the context of NCD drugs.

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[13] Here, "upward harmonization" means both a harmonization toward the new "minimum" standards of TRIPS that have been in place since the 1990s, as well as the ongoing push to make those standards more exacting. For more on the term "harmonization" as used in this context, see, for example, Amy Kapczynski, *Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 CALIF. L. REV. 1571 (2009). On efforts to render the TRIPS framework more stringent through the outright supplementation by so-called TRIPS-plus rules, see *infra* notes 41 and 51.

II. PRELUDE: THE GLEEVEC CASE IN INDIA

We start with the most significant example of a developing country—India—breaking from strict IPR for NCD drugs in recent years. In 2013, after years of controversy, India's Supreme Court upheld an administrative decision to deny Swiss Pharmaceutical giant Novartis a patent for Gleevec, a blockbuster cancer drug.[14]

The patent for Gleevec's underlying compound, known chemically as imatinib, was first filed in Switzerland in 1992.[15] By 1997, Novartis created the salt version of imatinib that was marketed as Gleevec.[16] In 1998, it applied for a patent on Gleevec in India with the Chennai branch of the Indian Patent Office (IPO).[17] As with the other controversies documented in Part V, the battle lines over Gleevec were drawn around the issue of whether the modifications Novartis made to the underlying compound made it a new invention.[18]

When Novartis applied for protection in India, its IP laws allowed only for process patents.[19] However, as an incoming WTO member state, India was required under TRIPS to also legalize product patents. After India passed relevant amendments to the India Patents Act in 2002 (and again in 2005), Novartis reapplied to the IPO for protection in 2005.[20]

In January 2006, the IPO issued a series of orders responding to five separate pre-grant oppositions to Novartis' application.[21] Under

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[14] Novartis v. Union of India & Others, A.I.R. 2013 S.C. 1311 (India).

[15] *Archive of Patent Applications for Imatinib and Derivatives,* EUR. PATENT OFFICE: ESPACENET, https://worldwide.espacenet.com/publicationDetails/inpadocPatentFamily?CC=US&NR=5521184A&KC=A&FT=D&ND=3&date=19960528&DB=worldwide.espacenet.com&locale=en_EP (last visited Nov. 10, 2017).

[16] *Information on European Patent No. WO9903854 (A1),* EUR. PATENT OFFICE: ESPACENET, https://worldwide.espacenet.com/publicationDetails/biblio?CC=WO&NR=9903854&KC=&FT=E&locale=en_EP (last visited Nov. 10, 2017).

[17] *See Novartis*, A.I.R. 2013 S.C. 1311 (India).

[18] *Id.*

[19] Kapczynski, *supra* note 13, at 1577.

[20] *Novartis*, A.I.R. 2013 S.C. 1311, at paras. 13–14 (India).

[21] Under four of these five orders, the commissioner determined that the invention Novartis was claiming had been anticipated by prior publication, that it

the most important of these orders, the IPO determined that Gleevec, a modified salt form of imatinib, did not pass muster under Section 3(d) of the Patents Act, which spells out criteria for "What are not Inventions."[22] Novartis appealed to India's newly formed Intellectual Property Appellate Board (IPAB) and filed two new petitions with the Madras Supreme Court—one challenging the constitutionality of Section 3(d) of the Patents Act and another its TRIPs-compliance.[23] The court dismissed both petitions in 2007.[24]

Notably, in the process, the IPAB reversed the IPO's declaration that the salt version of imatinib had been anticipated in earlier patent filings outside of India; it also reversed the declaration that the modified drug failed to qualify as a non-obvious invention.[25] However, the IPAB endorsed the IPO's decision that Novartis failed to clear Section 3(d)'s "requirement of higher standard of inventive step [sic]" and its more stringent standards for what counted as "patentable in India."[26] Thus, the IPAB backed the Madras High Court's view upholding the constitutionality of Section 3(d) and its underlying aim of "prevent[ing] evergreening" and "provid[ing] easy access to the citizens of the country to life saving drugs."[27]

Novartis next leapfrogged to the High Court, bringing a subsequent challenge directly to India's Supreme Court in 2011.[28] After more than two years of proceedings, with much fanfare and

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was obvious to a person skilled in the art in light of previously published patents, that the priority date of July 18, 1997, had been wrongly claimed for the patent application in India, and, therefore, that the alleged invention had also been anticipated by the specification made in the Swiss application. *Id*. at para. 14.

[22] *Id*.

[23] *Id.* at para. 15.

[24] *Id.*

[25] *Id.* at para. 17.

[26] *Id.* at para. 17 (quotations omitted). Since the *Novartis* decision, India has pressed its defense of the Supreme Court's view of the notion of inventive step to the World Intellectual Property Organization (WIPO). For its considered submission, see STANDING COMM. ON THE LAW OF PATENTS, WORLD INTELLECTUAL PROP. ORG., STUDY ON INVENTIVE STEP, SCP/22/3 (July 6, 2015), http://www.wipo.int/edocs/mdocs/scp/en/scp_22/scp_22_3.pdf.

[27] *Novartis*, A.I.R. 2013 S.C. 1311 at para. 18.

[28] Novartis took advantage of Article 136 of the Indian Constitution to seek a Special Leave Petition, arguing that any patent's expiry was soon approaching in 2018. *Id.* at para. 21.

controversy, in 2013 the Court denied Novartis a product patent on Gleevec one last time. Although the decision was lengthy and complex, it turned on the implications of what the Court called the "redefin[ition of] the concepts of invention and patentability" in Section 3 of the amended Patents Act.[29]

In addressing Section 3(d), the Court concluded that the salt version of imatinib was not an "invention" under the Patents Act of 1970.[30] It then went on to consider whether the salt qualified as an invention in its own right. Here, while the Court accepted that the salt could be counted as "new," it did not further consider whether it qualified as an "inventive step,"[31] deeming the issue moot because Gleevec "directly runs into section 3(d)" of the Patents Act.[32] The Court further elaborated that under Section 3(d), "inventions" must enhance "the known efficacy" of a substance.[33] Rather, for a drug like Gleevec, the very "function, utility, or . . . purpose" of which was to act as a medicinal therapy, "efficacy" could only mean therapeutic efficacy.[34] Accordingly, mere physico-chemical

[29] *Id.* at para. 24. Under the subtitle "What are not Inventions," after the 2005 amendment, the section reads as follows: "The following are not inventions within the meaning of this Act, —(d) the mere discovery of a new *form* of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property . . . ." The Patents (Amendment) Act, 2005, § 3(d), No. 15, Acts of Parliament (India).

[30] *Novartis*, A.I.R. 2013 S.C. 1311 at para. 131 ("[W]e are completely unable to see how Imatinib Mesylate can be said to be a new product, having come into being through an 'invention' that has a feature that involves technical advance over the existing knowledge and that would make the invention not obvious to a person skilled in the art. Imatinib Mesylate is all there is . . . . It is a known substance from the [previous] patent.").

[31] *Id*. at para. 158.

[32] *Id*.

[33] *Id.* at para. 180.

[34] The Court determined that the "test of efficacy in the context of section 3(d) would" not be the traditional dictionary definition of efficacy. As it further explained, "in the case of a medicine that claims to cure a disease, the test of efficacy can only be 'therapeutic efficacy' . . . judged strictly and narrowly." *Id*.

properties like "more beneficial flow" or "increased bioavailability" were held to not be efficacy enhancing under Section 3(d).[35]

With this ruling, the Court endorsed the more robust standard of patentability for modifications to existing compounds that the Patents Act mandated after being amended to comply with TRIPS.[36] At the same time, its stance was intentionally equivocal. The Court thus highlighted not one, but *two* ways that Section 3(d) could be read to heighten the bar for protection: first, as a provision "setting up the standards of 'patentability,'" and second, by "exten[ding] the definition of 'invention.'"[37]

The pharmaceutical industry immediately accused India of showing a general hostility to IPR, the TRIPS, and fair play by requiring a "second tier" criterion for pharmaceuticals to qualify as patentable.[38] Not surprisingly, then, the case was, and is, hardly limited to its import to India alone. Since 2010 it has become the tip of a larger iceberg of cases where developing countries are challenging strict patent rights of drugs for non-communicable conditions like cancer and cardiovascular disease, which is further discussed in Part V.

While the Gleevec case is an example of developing countries setting up higher standards of patentability, other mechanisms—like compulsory licensing—have figured prominently in forming the proverbial iceberg as well.[39] As documented in Part VI, and as summarized in Tables 1 and 2 below, the Gleevec case is hardly an isolated phenomenon. Is it, however, simply a coincidence that these all involve drugs for NCDs rather than for infectious diseases? In the remainder of this Article, I argue that it is not.

Rather, there is a fundamental shift afoot in the debate on access to medicines and patents due to a new form of strategic action that

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[35] *Id*. at paras. 187–89. On the issue of bioavailability, the Court held that bioavailability had to be "specifically claimed and established by research data." *Id*. at para. 189.

[36] Amy Kapczynski, *Engineered in India-Patent Law 2.0*, 369 NEW ENGL. J. MED 497, 497–98 (2013).

[37] *Novartis*, A.I.R. 2013 S.C. 1311 at para. 190.

[38] Interestingly, the Court peremptorily addressed this very accusation at length. *See id*. at paras. 103–04.

[39] *See infra* Part VI.

developing countries are now undertaking. In trying to comprehend this shift, however, we must first step back from the specificities of individual cases and controversies. In doing so, we will be able to broaden our perspective in two key ways. First, we will see how the traditional drugs-for-the-developing world debate first materialized and how it became emblematic of the supposedly zero-sum tradeoff between access and incentivization. Second, we will see why the shifting facts of the public health crisis in the developing world demand law and policy makers to re-theorize the relationship between the norms of access and incentivization in precisely the way developing countries have been asking by breaking with strict IPR for NCD drugs.

Table 1: Recent Challenges to NCD-drug Patents based on Heightening Bar for Patentability[40]

Country Disease Dates of Case	Generic Name Trade Name Drug Company	Modification	Adjudicating Bodies	Relevant legal reference
#1 India • Cancer • 2006-2013	• Imatinib • Gleevec • Novartis	Beta crystalline mesylate salt form of drug	• India Patent Office • Intellectual Property Appellate Board • Madras Supreme Court	Section 3(d) of India Patents Act of 1970; 2002 amendments
Unconstitutional under 3(d); drug does not meet "higher standards of inventive step" and does not "prevent evergreening"				
#2 India • Cancer • 2008- ??	• Lapatinib • Tykerb • GlaxoSmithKlein	Ditosylate salt form of drug	• Kolkata Controller of Patents • Intellectual Property Appellate Board	Section 3(d) of India Patents Act of 1970; 2002 amendments
Salt form of drug not a new invention under 3(d); IPAB helps set higher standard of patentability for modifications				
#3 India • Cancer • 2005-2014	• Paclitaxel • Abraxane • AbraxisBioScience	Drug gets bound to albumin allowing it to now be injected	• India Patent Office • Intellectual Property Appellate Board	Section 3(d) of India Patents Act of 1970; 2002 amendments
Fails on 3(d); lacks an inventive step; modification does not enhance therapeutic efficacy				
#4 India • Diabetes • 2007-present	• Sitagliptin • Januvia/Janumet • Merck	Phosphate salt form of drug	• India Patent Office • Delhi High Court	Section 3(d) of India Patents Act of 1970; 2002 amendments
Delhi High Court denies Merck's request for interim injunction by a generics manufacturer stating salt form of drug is not patented; Merck states original attempt to patent salt form of drug was "misguided"				
#5 Philippines • Cardiovascular Disease • 2009-present	• Atorvastatin • Lipitor/Apopitar • Pfizer	Salt form of drug	• Regional Trial Court of Makati • Court of Appeals	Section 22/26.2 of R.A. 8239 [Similar to 3(d) law]
Salt form of drug is a "frivolous" invention that doesn't pass R.A. 8239; Pfizer's request for temporary injunction is denied				
#6 Philippines • Epilepsy • 2009-present	• Pregabalin • Lyrica • Pfizer	Secondary Patent	• Wash DC Circuit	Section 22/26.2 of R.A. 8239 [Similar to 3(d) law]
Companies seek FDA approval for generic versions claiming patent is on a method of use; Court denies generics until 2018				

[40] For discussion of the information in Table 1 and Table 2, see *infra* Part VI.

Table 2: Recent Challenges to Strict NCD-drug patents based on Compulsory Licensing

Country	Drugs	Government Body	Legal Reference	Issue	Outcome
Thailand 2007-8	Kaletra Efavirenz Plavix Gleevec Docetaxel Erlotinib Femara	• Public Health Ministry	Thailand Patent Act, Section 51	Public vs. commercial use of drugs	Kaletra licensed; all others pending
India 2011	Nexavar	• Controller General of Patents, Desigs & Trademarks • Delhi High Court • Bombay High Court • India Supreme Court	India Patent Act Section 84(1)(c) Section 84(1)(b)	Drug availability to the public at a reasonable cost Drug must be locally worked	License fully executed
India 2013-14	Trastuzumab Ixabepilone Dasatinib	• Union Health Ministry • Department of Industrial Property and Promotion (DIPP) • Delhi High Court	India Patent Act Section 92	Biosimilar controversy National emergency/extreme urgency/public non-commercial use provisions	All cases have suffered legal setbacks
Ecuador 2009-present	32 applications by 2014 for a variety of NCD drugs beyond cancer	• Institute of Intellectual Property (IEPI)	Article 363(7) of Constitution Executive order 118	State to guarantee availability and access to quality medicines Licenses to be granted for reasons of public interest, emergency, and national security	9 licenses granted thus far

III. STAGING THE ACCESS-INCENTIVIZATION DILEMMA: THE LINKED HISTORIES OF FREE TRADE LIBERALIZATION AND THE DRUGS-FOR-THE-DEVELOPING WORLD DEBATE

Before discussing the developing world's NCD crisis, Part III begins by summarizing how the drugs-for-the-developing world debate co-evolved with the rebuilding of the legal framework during the post-Cold War economic liberalization. As the reader will see, the linking of these histories has been crucial in making the theoretical tension between pharmaceutical access and incentivization appear intractable.

This narrative must begin with the founding of the WTO in 1994, amidst euphoria over a new world order (rhetorically) premised on harmony and globalization. However, this euphoria began to dampen within the WTO's first decades of existence as "politics" quickly began taking over "economics" as the governing factor in world affairs after the terrorist attacks on September 11, 2001. Early difficulties were clearly evident by 2004 with the stymying of efforts to extend the spirit of multilateralism to the liberalization of new areas like investment and financial services.[41] Negotiations through the WTO process itself were also beset by conflict, especially over agricultural subsidies.

Since 1994, the modern world has only once moved towards more circumscribed regional/bilateral agreements as a second-best alternative for advancing liberalization.[42] Between this first retreat from a more ambitious agenda of multilateral globalization and our now impending reversion to the same tendency in the wake of

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[41] *E.g.*, Agreement on Trade-Related Investment Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1868 U.N.T.S. 186.

[42] *See* Mohammed El-Said, *The Road from TRIPS-Minus, to TRIPS, to TRIPS-Plus: Implications of IPRs for the Arab World*, 8 J. WORLD INT. PROP. 53 (2005); Pedro Roffe, *Bilateral Agreements and a TRIPS-Plus World: the Chile-USA Free Trade Agreement*, TRIPS-ISSUES PAPERS 4 (2004), http://law-wss-01.law.fsu.edu/gpc2007/materials/roffe_ottowa2004.pdf; David Vivas-Eugui, *Regional and Bilateral Agreements and a TRIPS-plus World: the Free Trade Area of the Americas (FTAA)*, TRIPS-ISSUES PAPERS 1 (2003), http://www.grain.org/fr/article/entries/3610-regional.pdf.

populist upsurge of 2016,[43] the pendulum has swung back in the other direction. By 2011, at the same time that talks for the now-defunct TPP were intensifying, parallel efforts to resume global integration on a multilateral basis were taking place through other treaties including the Trans-Atlantic Trade and Investment Partnership, the Trans-Atlantic Free Trade Agreement, and the Trade in Services Agreement.[44] Additionally, bilateral treaties with major economic powers like Korea and China were also either approved or actively pursued in the last five years.[45]

Given the oscillations between multilateralism and bilateralism within our ongoing era of post-Cold War globalization, it is easy to forget that we are still only a generation removed from the controversy the WTO ignited around IPRs and access to medicines. Before 1994, while many developing countries allowed process patents, TRIPS-compliance required WTO member states to allow for product patents as well (and, as with process patents, in any field of technology including pharmaceuticals).[46] Concerns about the impact of IPRs—and specifically, patents—on public health in the developing world thus achieved broad social penetrance only after the Uruguay round of negotiations of the General Agreement on Tariff and Trades (resulting in the WTO). Moreover, it was only two years later in 1996 that the first truly effective anti-retroviral

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[43] While the future is unclear, the Trump administration and conservatives in Britain appear to be moving toward bi- or scaled-down multi-lateralism. *See, e.g.*, Alan Wolff, *Free Trade Is Not Dead Under Donald Trump*, FORTUNE (Dec. 15, 2016), http://fortune.com/2016/12/15/free-trade-donald-trump-tpp.

[44] *See* Robert E. Lutz, *Linking Trade, Intellectual Property and Investment in the Globalizing Economy: The Interrelated Roles of FTAs, IP and the United States*, *in* INTELLECTUAL PROPERTY AND FREE TRADE AGREEMENTS IN THE ASIA-PACIFIC REGION 155–70 (Christopher Antons & Reto M. Hilty eds., 2015); Peter K. Yu, *Déjà Vu in the International Intellectual Property Regime*, *in* THE SAGE HANDBOOK OF INTELLECTUAL PROPERTY 113–29 (Matthew David & Debora Halbert eds., 2014).

[45] While the idea of a trans-Atlantic free trade area goes back to the 1990s, the idea was revived by German Chancellor Angela Merkel in 2007 and pursued in earnest only after 2011. *See* James Kanter & Jack Ewing, *A Running Start for a U.S.-Europe Trade Pact*, N.Y. TIMES (Feb. 13, 2013), http://www.nytimes.com/2013/02/14/business/global/obama-pledges-trade-pact-talks-with-eu.html.

[46] TRIPS Agreement, *supra* note 7, at art. 27.1.

therapies for HIV/AIDS became available.[47] As many recall, a turning point was reached in 1999 when global health activists targeted then Presidential-hopeful Vice President Al Gore for silence over the pharmaceutical lobby's efforts to limit South Africa in making the AIDS/HIV "triple cocktail" available to its citizens.[48]

Subsequently, the drive toward upward harmonization of national IP regime design became more controversial as the deadline for developing countries to comply with TRIPS approached (in 2005).[49] The drugs-for-the-developing world controversy thus increasingly became TRIPS' legacy, especially for civil society actors and the public.[50] Already by 2001, at its Ministerial Conference in Qatar, the WTO was compelled to issue its famed Doha Declaration on TRIPS and Public Health, which was meant to confirm the availability of various "exceptions" to strict IPRs.[51] While the Doha Declaration did partially quell concern, worries remained.[52] Indeed, no sooner did member states endorse TRIPS-flexibility in Qatar than the push for so-called TRIPS-plus protections started to appear.[53]

By the late 2000s, the TRIPS-plus agenda was increasingly becoming a default position in ongoing negotiations for Trans-Atlantic and Trans-Pacific integration. Therefore, at least one trend that has been evident since 2011 will likely survive a return to

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[47] Jintanat Ananworanich & Joep M.A. Lange, *The Discovery and Development of Antiretroviral Agents*, 19 ANTIVIRAL THERAPY (SUPPLEMENT 3) 5, 6 (2014), https://www.intmedpress.com/serveFile.cfm?sUID=c47b3504-6207-4956-a8d2-2e344a807db6.

[48] Julian Borger, *Gore Accused of Working Against Cheap Aids Drugs*, THE GUARDIAN (Aug. 10, 1999, 20:47 EDT), https://www.theguardian.com/world/1999/aug/10/uselections2000.usa.

[49] The transition period, which has been extended for some countries, actually varied for different categories of developing countries. *See* TRIPS Agreement, *supra* note 7, at arts. 65, 66.

[50] DAVID HULME, GLOBAL POVERTY: GLOBAL GOVERNANCE AND POOR PEOPLE IN THE POST-2015 ERA 188–89 (2d ed. 2015).

[51] World Trade Org., Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration].

[52] *See* Charles T. Collins-Chase, *The Case Against Trips-Plus Protection in Developing Countries Facing Aids Epidemics*, 29 U. PA. J. INT'L L. 763 (2008).

[53] *Id.*

bilateral free trade under a Trump administration.[54] Namely, this trend is the continued pursuit of a TRIPS-plus agenda will occur side by side with a period in which conflict over drug patents in the developing world has become more acute than at any time since the Doha Declaration. Indeed, even though countries like India and Thailand never fully lost their place on the United States Trade Representative's (USTR) Priority Watch List for allegedly creating barriers to trade, criticism of their IPR policy reached new heights in the last five to six years.[55]

It is only against this larger backdrop that we can understand how popular and scholarly discussion has come to portray the relationship between patents and public health as intractable.[56] Indeed, part of the reason behind this assumption is that the normative dilemma imposed by the supposedly imminent tradeoff between pharmaceutical access and incentivization has always been three-fold. First, there is the normative demand of the new legal regime enshrined in the TRIPS agreement. As a result, we ask not about whether strict IPR/upward harmonization *should be* the norm so much as how far countries *should be* allowed to move away from the TRIPS rule through exceptions/flexibilities. Second, there is the normative demand of neoclassical economic theory. As a result, we tend to ask less about whether patents incentivize innovation than we do about how far economic theory, as if speaking in one voice, *should be* our only guide. It is only in a third and final sense that the demand to decide how we *should* tradeoff long-term economic

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[54] If the impending talks about the fate of the North American Free Trade Agreement (NAFTA) are any guide, this may have already started to be borne out. *See, e.g.*, Nicholas Caivano & Richard Elliott, *Warning – A New NAFTA Could Prevent Vital Medicines Getting to Millions Worldwide*, OTTAWA CITIZEN (Aug. 19, 2017, 8:00 AM EDT), http://ottawacitizen.com/opinion/columnists/caivano-and-elliott-warning-a-new-nafta-could-prevent-vital-medicines-getting-to-millions-worldwide.

[55] The Priority Watch List is part of the "Special 301 Report" the USTR issues annually. *See* Judith H. Bello & Alan F. Holmer, *Special 301: Its Requirements, Implementation, and Significance*, 13 FORDHAM INT'L L.J. 259 (1989); *see also* Sean M. Flynn, *Special 301 of the Trade Act of 1974 and Global Access to Medicines*, 7 J. GENERIC MED. 309 (2010).

[56] *See, e.g.*, George Wehrfritz, *Thailand's New Drug War*, NEWSWEEK (Apr. 8, 2007, 8:00 PM), http://www.newsweek.com/thailands-new-drug-war-97635.

rationality and immediate-term ethics—in a world where avoiding harm means avoiding infectious diseases—becomes normative dilemma's most visible face.

In the face of this seeming intractability at the heart of our existing drugs-for-the-developing world debate, it seems that opposition to the upward harmonization of national IP regime design is not only growing but also increasingly fragile.[57] Indeed, ever since the founding of the WTO, the burden of proof has always been firmly on those demanding less strict approaches to patents rather than vice versa. The first-ever amendment to TRIPS, created in January 2017, is telling in this regard. While it waives the requirement that licenses issued to create generic versions of on-brand drugs should be restricted to a country's own local market, it simultaneously confirms how TRIPS' "flexibility" has not only been uncertain and largely unused for more than sixteen years but also how its future use is likely to remain tightly restricted.[58]

Therefore, our overall existing drugs-for-the-developing world debate has produced a double-edged sword. Advocating for access to "essential medicines" through the exceptionality of TRIPS-flexibilities has clearly been crucial. At the same time, some argue that the access-incentivization dilemma is so acute that departing from strict IPR would be an inevitable health crisis.

IV. "DISEASES OF CIVILIZATION" GO GLOBAL: THE BURGEONING CRISIS OF NON-COMMUNICABLE DISEASE IN THE DEVELOPING WORLD

Falling under the heading of NCDs are conditions such as cancer, arteriosclerosis and other cardiovascular ailments, mental illness, asthma and other chronic respiratory diseases, and a host of other afflictions including type 2 diabetes, cirrhosis, and chronic renal failure. Using data from 2008, in its first (and most recent) global action plan on such conditions, the World Health

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[57] *See* Ellen Hoen et al., *Driving a Decade of Change: HIV/AIDS, Patents, and Access to Medicines for All*, 14 J. INT'L AIDS SOC'Y 1 (2011).

[58] World Trade Org., *WTO IP Rules Amended to Ease Poor Countries' Access to Affordable Medicines,* WTO.ORG (Jan. 23, 2017), https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm.

Organization (WHO) estimates that out of the 56 million annual global deaths that occurred in 2008, some thirty-six million—or nearly 63%—were due to NCDs.[59]

Traditionally seen as burdens on the health of developed country populations alone, NCDs have been called both "diseases of civilization" and "lifestyle" ailments. Accordingly, they are generally linked to the patterns of diet, work, and leisure that characterize the relatively more prosperous societies of the Global North.

A. *NCD-Related Health Loss in the Developing World*

Such an impression, however, is mistaken—as the just-cited figures from the WHO's Global Action Plan on NCDs make clear when broken down according to the location in which deaths occurred .[60] Already by 2008 only 20%—or seven million—of the thirty-six million NCD-related deaths that year occurred in high-income countries, a group the WHO defines to include North America outside of Mexico, Western Europe, Saudi Arabia, Qatar, Japan, Korea, Australia, New Zealand, Singapore and a handful of other countries.[61] As Figure 1 shows, the other 80% of global NCD-related deaths in 2008—making for a total of twenty-nine out of the thirty-six million total—took place in low and middle-income countries.[62]

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[59] World Health Org., Global Action Plan for the Prevention and Control of Noncommunicable Diseases: 2013–2020 (adopted 2013) [hereinafter WHO, *Global Action Plan*].

[60] *Id.*

[61] The WHO's full list includes the Bahamas, Bahrain, Kuwait, United Arab Emirates, and Brunei Darussalam. World Health Org., Global Burden of Disease: 2004 Update (2008) [hereinafter *Global Burden of Disease*]. According to the World Bank's Atlas method, high-income countries have a gross national income per capita above $12,476 (measured from 2015). There are currently seventy-nine such countries. *World Bank Country and Lending Groups*, THE WORLD BANK, https://datahelpdesk.worldbank.org/knowledgebase/articles/906519#High_income (last visited Feb. 11, 2017).

[62] These two categories comprise the remainder of the world's countries for the WHO. In 2015 terms, its thirty-one current "low-income" countries have gross national incomes per capita of $1,025 or less (and includes places like Afghanistan, Ethiopia, Haiti, Mali, Nepal, and Uganda); its fifty-two lower-

Longitudinal data provides more compelling evidence of NCD burden on the developing world. By 1990, only 40% of the total number of worldwide NCD-related deaths occurred in low and middle-income countries, but by 2008, the proportion doubled to 80%.[63] Furthermore, future projections estimate that by 2030 low and middle-income countries will suffer fifty-five million annual NCD-related deaths.[64]

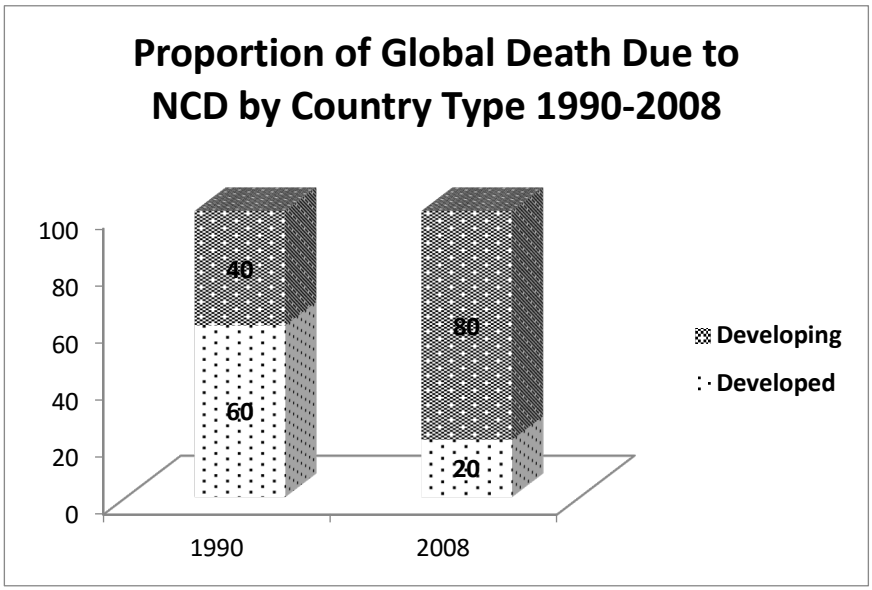

Figure 1

In addition to suffering from an increasing proportion of total global deaths, developing countries' inhabitants will also die of

middle-income countries have gross national incomes per capita of $1,026 to $4,035 (and includes places like Bangladesh, Cambodia, Honduras, India, Morocco, Uzbekistan, and Zambia); its fifty-six current upper-middle-income countries have gross national incomes per capita of $4,036 to $12,475 (and includes places like Albania, Argentina, Ecuador, Lebanon, and Thailand). *Id.*

[63] *WHO Mortality Database,* WORLD HEALTH ORG. (2017), http://www.who.int/healthinfo/mortality_data/en/.

[64] WHO*, Global Action Plan*, *supra* note 58, at 7.

NCD deaths at an earlier age.[65] For example, in 2008, NCD-related deaths accounted for 48% and 26% of deaths for persons under age 70 in the developing and developed worlds, respectively.[66]

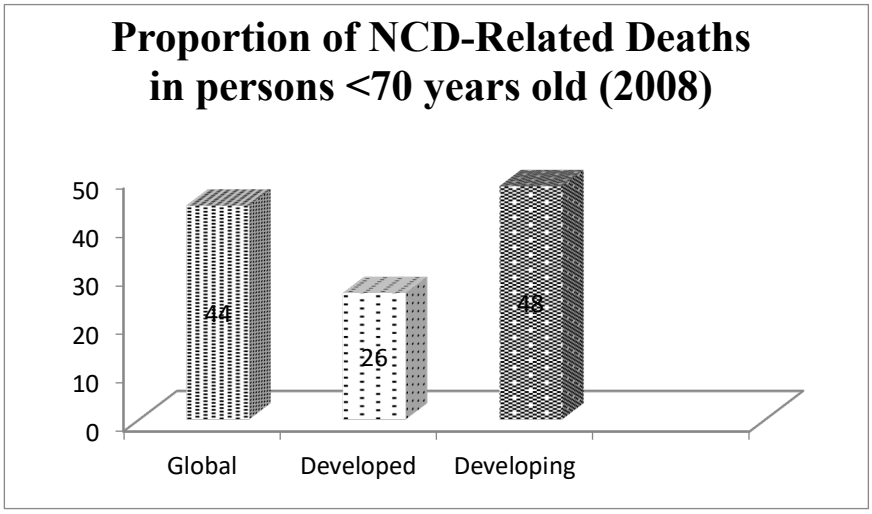

Figure 2

Looking beyond actual deaths, a similar story is borne out by assessing the impact of NCDs through the more nuanced metric of disability-adjusted life years (DALYs). Developed in the early 1990s by the World Bank and researchers at Harvard University, the DALY has increasingly been adopted as a standard[67] because it is meant to capture the years of life lost due to premature deaths (YLLs), as well as the years of life lost due to disability or poor

[65] D.E. BLOOM ET AL., WORLD ECON. FORUM & HARV. SCH. OF PUB. HEALTH, THE GLOBAL ECONOMIC BURDEN OF NON-COMMUNICABLE DISEASES (2011) [hereinafter HSPH-WEF, *The Global Economic Burden*].

[66] *Global Health Observatory (GHO) Data: Premature NCD Deaths*, WORLD HEALTH ORG., http://www.who.int/gho/ncd/mortality_morbidity/ncd_premature_text/en/ (last visited Feb. 11, 2017).

[67] *See* ALAN D. LOPEZ ET AL., GLOBAL BURDEN OF DISEASE AND RISK FACTORS 3–4 (2006); Christopher Murray, *Quantifying the Burden of Disease: The Technical Basis for Disability-Adjusted Life Years*, 72 BULL. WHO 429 (1994).

health (YLDs).[68] Equivalent to one lost year of "healthy" life, the DALY thus represents a measure for quantifying the absolute health loss resulting from both mortality and morbidity.

Based on the most current figures, as measured in DALYs, total annual health loss in 2010 reached 2.49 billion, 31% of which came from YLDs and the remaining 69% from YLLs.[69] During the last two decades, there has also been a marked overall decline—of 23%—in health loss per 1000 persons, from 472 DALYs in 1990 to 361 in 2010,[70] as well as a sizeable increase in the percentage composition of DALYs comprised by YLDs over YLLs.[71]

More important are the changes between 1990 and 2010 to the respective contributions that NCDs have made to cumulative global health loss. As Figure 3 shows, DALYs from NCDs have increased in the developing world over the last twenty years (from 36% to 49%) but remained unchanged (at 83%) in the developed world during the same time period.[72] This was almost entirely due to the increasing share of lost DALYs from NCDs in the developing world.[73]

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[68] YLL's are calculated by multiplying the number of deaths from a given disease and a standard life expectancy for the age at which death occurs. YLD's are calculated by multiplying the number of incident cases in a given period, the average duration in years of the disease case (until remission or death), and a "disability weight," a factor reflecting disease severity on a scale from 0, representing perfect health, to 1, representing the state of being dead. LOPEZ ET AL., *supra* note 67. Since its 2010 Global Burden of Disease study, the WHO has modified this formula, with the YLD now reflecting the product of the disability weight and the number of prevalent cases (rather than the product of incident cases and case duration). *Health Statistics and Information Systems-Metrics: Disability-Adjusted Life Year*, WORLD HEALTH ORG., http://www.who.int/healthinfo/global_burden_disease/metrics_daly/en/ (last visited Feb. 11, 2017).

[69] Christopher J.L. Murray et al., *Disability-Adjusted Life Years (DALYS) for 291 Diseases and Injuries in 21 Regions, 1990–2010: A Systematic Analysis for the Global Burden of Disease Study 2010*, 380 THE LANCET 2197, 2210 (2012).

[70] *Id*. at 2198, 2202.

[71] *Id*. at 2213 (Figure 6).

[72] *Id*. at 2198.

[73] *GBD (Global Burden of Disease) Compare, Data Visualization Tool*, INST. OF HEALTH METRICS & EVALUATION, http://vizhub.healthdata.org/gbd-compare/ (last visited Feb. 11, 2017). Of course, there remains a large degree of epidemiological variation. *See* Murray, *supra* note 69, at 2214.

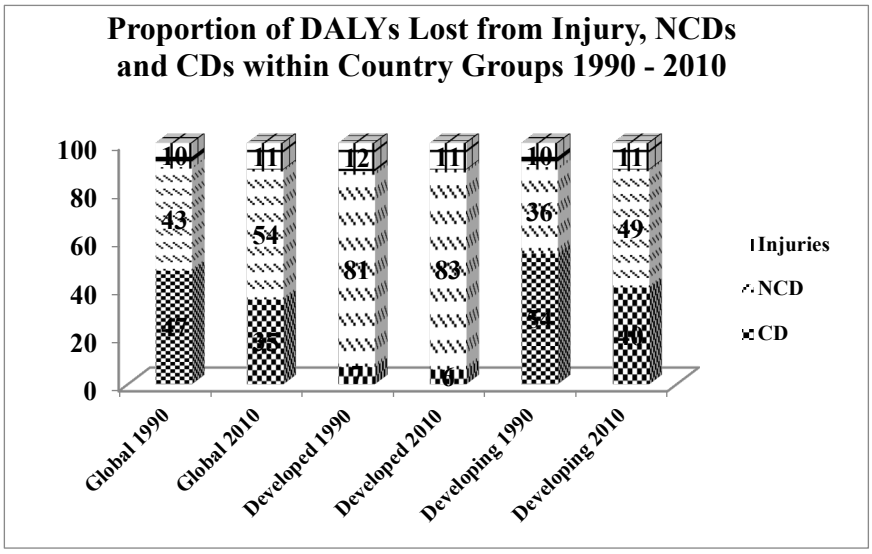

Figure 3

Of course, this is not to deny that there is some truth to the notion that NCDs are diseases of the rich. For example, relative to overall mortality burden within different country groups—whether measured in DALYs or actual deaths—NCDs are responsible for more of the total in high-income societies than in the low and middle-income ones.[74] Likewise, within the developing world, it is those with higher income who are more likely to be afflicted by NCDs.[75] However, both of these facts must be balanced against two others. First, as noted above, a greater absolute number and a more rapidly increasing share of total deaths due to NCDs are now taking place within the developing world. (These sources of disparity, moreover, will remain constant or increase in the future given the higher rate of population growth in developing countries.) Second,

[74] *Global Burden of Disease*, *supra* note 61, at 11.

[75] HSPH-WEF, *The Global Economic Burden*, *supra* note 65, at 11. The correlation is not fixed. In low and middle-income countries, the poorest can also become the more seriously afflicted by NCDs. *See* Marc Suhrcke et al., CHRONIC DISEASE: AN ECONOMIC PERSPECTIVE (Oxford Health Alliance ed. 2006).

within the low and middle-income country groups, less-affluent inhabitants are more likely to die once afflicted by any given NCD.[76]

B. *NCD-Related Economic Loss in the Developing World*

As is the case for the burdensome effect of disease in general, there can be little doubt of a close connection between health and economic loss due to NCDs. The most obvious example of this phenomenon is seen in the growing role of YLDs over YLLs in the global composition of DALYs lost due to NCDs.[77] In the developing world in particular, the close connection between health and economic loss due to NCDs is evidenced by the large and growing share of the mortality burden shouldered by individuals of reproductive[78] or otherwise still working age.[79] In an important 2005 study of the top 23 contributors to NCD-related health loss in the developing world (that were responsible for some 80% of the developing world's total), it was projected that in the period from 2006 to 2015 the cost of lost national income from diabetes, stroke, and heart disease alone would reach $84 billion.[80]

More recent attempts at examining economic loss have proven even more eye-opening. They have also proved increasingly sophisticated in terms of methodology, generally distinguishing lost output and value of statistical life approaches for tabulating economic loss from so-called "cost of illness" approaches.[81] The best

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[76] HSPH-WEF, *The Global Economic Burden*, *supra* note 65, at 11.

[77] Murray, *supra* note 69, at 2213.

[78] *Id.* at 2215. The reproductive age group generally ranges from ages 15–49. *Id.* at 2211.

[79] Suhrcke, *supra* note 75, at 11 (estimating that 80% of chronic NCD-DALY's in low and middle-income countries are 60 years old or younger).

[80] Dele O. Abegunde et al., *The Burden and Costs of Chronic Diseases in Low-Income and Middle-Income Countries*, 370 THE LANCET 1929, 1929 (2007).

[81] Value of lost output approaches focus on how NCDs affect gross domestic product (GDP) through considering the role of disease in depleting a country's factors of production, including labor and capital. HSPH-WEF, *The Global Economic Burden*, *supra* note 65, at 14. Cost of illness approaches look at both direct and indirect NCD costs and consider factors like personal medical expenses from diagnostic procedures, drugs, and inpatient/outpatient care; non-medical expenses like for transportation for treatment; non-personal costs of information, education, and research; and the loss of income. *Id.* The value of statistical life

of these studies—by the Harvard School of Public Health (HSPH) in conjunction with the World Economic Forum (WEF) —provides three separate projections for cumulative economic loss from NCDs for the twenty-year period from 2010 to 2030: lost output and value of statistical life (shown in Table 3) and cost of illness approach (shown in Figure 4).

For lost output, the HSPH-WEF study finds that cancer, cardiovascular disease, diabetes, chronic respiratory disease, and mental illness will cost low and middle-income countries an enormous $21 trillion versus $25.5 trillion for high-income countries over the same period.[82]

For the statistical life approach, the HSPH-WEF study tallies a figure of $23.8 trillion in projected economic loss for low and middle-income countries between 2010 and 2030 versus $20 trillion in loss for high-income countries for the same time period.[83]

Table 3: Economic Loss from NCDs 2010 to 2030*

Measure	Low to Middle-Income Countries	High-Income Countries
Lost output	$21 Trillion	$25.5 Trillion
Value of Statistical Life	$23.8 Trillion	$20 Trillion
Annualized % Loss to World Nominal Product	3.9% to 4.4%	2.1% to 2.7%

**Sources: HSPH, WEF, World Bank*

On either approach, the HSPH-WEF study finds the average expected annual cost to low and middle-income countries to be more than $1 trillion (that is, $21 trillion or $23.8 trillion divided by 20

approach reflects a given population's willingness to pay for reducing the risks of NCD disability/death. *Id.*

[82] *Id*. at 29 (calculating in US$ 2010).

[83] *Id.* at 33.

years). This annualized amount can be compared to the World Bank's latest data on low and middle-income countries' contribution to the world nominal product for 2015 ($27 trillion out of $74 trillion).[84] Holding these figures constant for simplicity's sake, low and middle-income countries would be expected to experience an average annual NCD-related economic loss of a striking 3.9% or 4.4% of their total contribution to world nominal product in any given year up to 2030.[85] This can be compared to the average annual loss to world nominal product of 2.1% or 2.7% that high-income countries would experience through 2030.[86] Moreover, this does not account for the premium that should be placed on each dollar lost in the developing world relative to each lost in the developed world, given the relative poverty of the former as compared to the latter and what it means for the "marginal utility" of what is lost.

While summarizing the HSPH-WEF findings based on a cost of illness approach is more difficult, the findings are largely in line with the overall trends indicated by two other measuring approaches. For example, the sum of the direct costs of diabetes in low and middle-income countries is expected to increase from a mere 9% to 75% from 2010 to 2030.[87] A similar, though less dramatic, story is true for the indirect costs associated with diabetes, which would increase from 50% to 76% from 2010 to 2030.[88] This is balanced against what is expected to be only a slight shift in the percentage of low and middle-income country inhabitants afflicted with diabetes, from 74% of the global total of 285 million people in

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[84] WORLD BANK, *GDP Ranking* (Feb. 1, 2017), http://data.worldbank.org/data-catalog/GDP-ranking-table.

[85] Lost output measure = US$21 trillion/20 years (world nominal product); statistical life measure = US$23.8 trillion/20 years (world nominal product). *Id.*

[86] Lost output measure = $US25.5 trillion/20 years (world nominal product); statistical life measure = $US20 trillion/20 years (world nominal product). *Id.*

[87] Conversely, the high-income country share of diabetes' direct costs incurred by high-income countries will drop from 91% of this total to only 25%. HSPH-WEF, *The Global Economic Burden*, *supra* note 65, at 25.

[88] Conversely, the high-income share of diabetes' indirect costs will drop from 50% to 24% of the total. *Id*.

2010 to 79% of a projected global total of 437 million persons in 2030.[89]

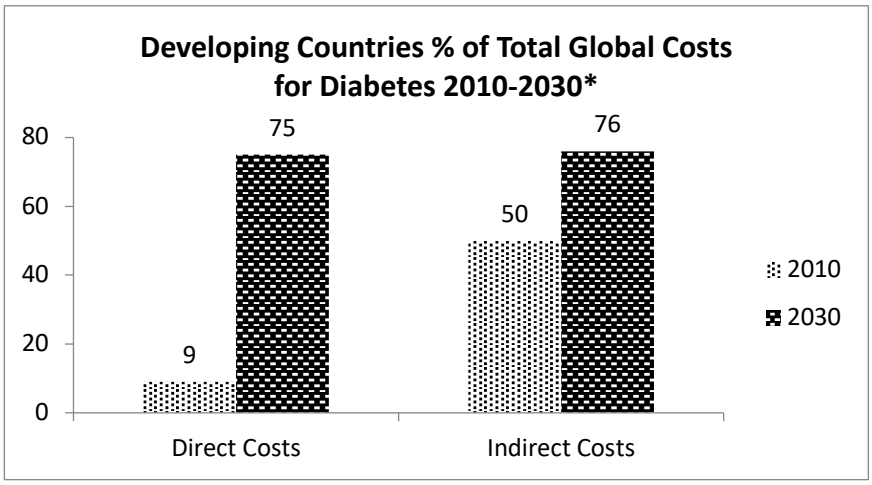

Figure 4

**Total Direct Costs worldwide increased from $376 Billion to $486 Billion*

**Total Indirect Costs worldwide increased from $96 Billion to $255 Billion*

While the cost of illness approach may provide less digestible aggregate headline figures, it is especially interesting because it reckons with both the direct and indirect costs of NCDs. Compared to other methods, it highlights that even though the drugs-for-the-developing world debate has focused on curative (pharmaceutical) interventions, addressing public health crises also involves creating better strategies for prevention. Indeed, relatively low-cost and non-drug based measures—like smoking cessation programs and cervical cancer screening—are particularly important for mitigating the burden of NCDs.[90] Consider, for example, the many preventative

[89] The corresponding high-income country share will fall from 26% of the global total (or 75 million people, as opposed to the developing world's 210 million) in 2010 to 21% (or 93 million people, as opposed to the developing world's 345 million) in 2030. *Id.*

[90] Shanthi Mendis et al., *Global Status Report on Noncommunicable Diseases (2014)*, WORLD HEALTH ORGANIZATION (2014), at 5, http://apps.who.int/iris/bitstream/10665/148114/1/9789241564854_eng.pdf.

interventions in the developed world that are built on generic drugs, such as using aspirin as a means of preventing cardiovascular illness.[91] Here, the lack of patent protection on the relevant therapeutic agent is hardly a starting point for discussion, much less anything that we would generally envision as an omen of some coming era devoid of medicines. In this respect, thinking about preventative intervention, in the same way that cost of illness accounting for NCD-related economic loss in the developing world encourages us to, is already a first step toward unfastening the straitjacket of the access-incentivization dilemma.

C. *The Importance of the High Price of NCD Drugs*

Notwithstanding the benefits of low-cost preventative intervention, there is no doubt that the high prices for NCD drugs are/will become a significant obstacle to better public health in the developing world like the high prices for communicable disease drugs have been.[92] There are a number of reasons for this. First, curative versus preventative measures cannot always be firmly distinguished by the presence or absence of drugs as part of the intervention design. As determined in the communicable disease context by HIV/AIDS, there only needs to be a single or otherwise small number of ailments that require costly drugs for their prevention to make patent-inflated pricing a key issue in the success of preventative intervention overall.[93] Therefore, the high prices that make it difficult even for developed world health agencies to increase the availability of preventative therapies, like human papilloma virus (HPV) vaccine, are guaranteed to be more

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[91] *Id*. at 63.

[92] In India, for example, 50% to 80% of expenditure for medical treatment is on medicines. S. Srinivasan, *'Medicines for All,' The Pharma Industry and the Indian State*, 46 ECON. & POL. WKLY. (June 11–17, 2011).

[93] Of course, HIV/AIDS drugs, unlike drugs for conditions like malaria, are the one example among communicable disease medications that have robust markets in the developed world. In this respect, they foreshadow why easing the developing world's access to NCD-drugs by moving away from strict approaches to patent rights would not pose any meaningful threat to the multinational pharmaceutical sector's incentives.

significant for low and middle-income countries because they will not have access to them.[94]

Second, there is the fact that the burden of NCDs is mounting in the developing world. As ailments like cancer and cardiovascular disease grow in prevalence, so too will the demand for generally higher priced drugs needed to treat them. Moreover, these drugs are generally more likely to retain their status as higher priced because it is these drugs that pharmaceutical firms have the strongest interests in protecting behind patent walls—at least, evidently, if the profits they profess to garner from consumer markets in high-income countries are to be believed.

Third, populations in the developed world are/will be living in the same age of declining R&D spending as those in the developing world. This is part and parcel of the increasing reliance by multinationals on lucrative "me-too" drugs that redirect funds toward marketing and advertising activities to differentiate such products from their largely equivalent competitors.[95] (From the consumer standpoint, spending that remunerates marketing budgets may be no more than a form of economic waste insofar as it leads not to innovation but artificial product differentiation perpetuating inflated prices for their own sake.[96]) Moreover, this tendency is likely to prolong the period in which patents on NCD drugs—and the inflated prices they allow—persist. To the extent that there is increasing pressure to engage in so-called evergreening, the significance that high prices for NCD drugs have on hindering

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[94] *E.g.*, H.V. Hogerzeil et al., *Promotion of Access to Essential Medicines for Non-communicable Diseases*: *Practical Implications of the UN Political Declaration*, 381 THE LANCET 680, 684 (Feb. 12, 2013).

[95] Arguments have been made that me-too drugs reduce consumer prices through competition. For an effort to quantify the tradeoffs (reaching mixed conclusions at best), see Stephane Régnier, *What is the Value of 'Me-Too' Drugs?*, 16 HEALTH CARE MGMT. SCI. 300 (Feb. 26, 2013).

[96] For a still useful overview of different positions, see Peter Doyle, *Economic Aspects of Advertising: A Survey*, 78 THE ECON. J. 570 (Sept. 1968). *See also* O.J. FIRESTONE, THE ECONOMIC IMPLICATIONS OF ADVERTISING (11th ed. 2013).

public health in the developing world will become more, and not less, intense.[97]

Finally, patent-inflated prices for NCD-drugs are/will become more important because they impose additional costs on health care systems that are rooted in the particular kind of innovation culture they encourage. For example, patents are ill-suited for capturing the social value created by preventative health interventions. This is because the non-pharmaceutical based "information goods" that such interventions either partly rely on or wholly consist of are highly "non-excludable" in nature, thus making it difficult to patent them.[98] As a result, an innovation culture focused on patents will tend to crowd out precisely those goods comprising the non-drug based means of preventative intervention that are most likely to compel a shift away from patent reliant/price-inflated pharmaceutical goods in the first place. As suggested earlier, this is particularly important in relation to NCDs given how much more significant preventative intervention generally is in mitigating the morbidity and mortality they cause.

V. THE ARGUMENT STRUCTURE OF NORMATIVE STALEMATE

Ultimately, the high prices that are made possible by the monopolistic tendencies of patent protections on NCD drugs raise two considerations pertinent to the argumentative structure of our existing drugs-for-the-developing world debate. The first concern is how the gains to multinationals from patented compounds should be classified—whether as ordinary producer surpluses, excessive supracompetitive profits,[99] or outright confiscatory economic

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[97] *See* Ralf Boscheck, *Intellectual Property Rights and the Evergreening of Pharmaceuticals*, 50 INTERECONOMICS 221 (July 2015). There is much dissatisfaction with the term "evergreening." However, it should not be mistaken for clarity as to patent extension being of no importance. *See* Douglas L. Rogers, *Double Patenting: Follow-on Pharmaceutical Patents that Suppress Competition*, 14 NW. J. TECH. & INTELL. PROP. 317 (2017).

[98] Amy Kapczynski & Talha Syed, *The Continuum of Excludability and the Limits of Patents*, 122 YALE L.J. 1900, 1905–16 (2013).

[99] "Supracompetitive profits" are generally understood as profits that are set at a higher level than what could be obtained in a "normal" competitive market. For a discussion in the legal context, see, for example, Phillip E. Areeda & Donald F.

rents.[100] The second deals with the extent to which these gains needlessly come at the expense of consumer surpluses that developing world inhabitants could otherwise recover through more robust markets for generics and increasing competition.[101]

By equating the problem of public health in the developing world with a crisis of infectious disease, these questions become easier to elide. For most of the period during which upward harmonization of national IP regime design has been the default in international economic law, lost consumer surplus has been either ignored or implicitly recast as a vanishing immediate-term cost. At best, the suggestion goes, such losses are outweighed in the long run by the benefits of financing the entry of new health-enhancing compounds onto the market. On this view, patent power is finite, and the near-term relationship between (confiscatory) producer and (confiscated) consumer surpluses will reverse in time. Once the patent ends, competition is projected to make the latter increase and the former decrease, especially as the volume of total sales expands as lower prices bring market expansion.[102] However, as I argue further below, such generalities provide even less guidance in the NCD context than they have in the communicable disease context

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Turner, *Predatory Pricing and Related Practices Under Section 2 of the Sherman Act*, 88 HARV. L. REV. 697 (1975).

[100] *See* Kevin Outterson, *The Vanishing Public Domain: Antibiotic Resistance, Pharmaceutical Innovation and Intellectual Property Law*, 67 U. PITT. L. REV. 67, 118 (2005) (explaining that pharmaceutical rents "come at a great cost to society"); *see also* Anup Mialani, *Reverse Settlements, Part 2: Drug Company Profits*, BILL OF HEALTH (Jan. 26, 2013), https://blogs.harvard.edu/billofhealth/2013/01/26/reverse-settlements-part-2-drug-company-profits/ (last visited Feb. 11, 2017) (describing that the amount spent by companies on R&D correlates with the total expected rents from the patents they may obtain).

[101] Outterson, *supra* note 100, at 72.

[102] For further reading on this theory, see Bruce N. Kuhlik, *The Assault on Pharmaceutical Intellectual Property*, 71 U. CHI. L. REV. 93 (2004). *See also How Patents Encourage Innovation in Technological Development and Deployment,* GLOB. GCS INST., https://hub.globalccsinstitute.com/publications/intellectual-property-rights-role-patents-renewable-energy-technology-innovation/1-how-patents-encourage-innovation-technological-development-and-deployment; *PhRMA Statement on Patent Reform Act of 2009*, PHRMA (Mar. 3, 2009), http://www.phrma.org/press-release/phrma-statement-on-patent-reform-act-of-2009.

as to how long we should tolerate the tradeoff,[103] which is the crux of the matter.[104] Judged by this most crucial issue, measures making IPR regimes stricter—as through standardizing twenty years as the minimum period for protection[105]—seem arbitrary.

It is worth noting that focusing the artificiality of the normative stalemate that the infectious disease perspective creates does not eliminate the tension between access and incentivization. There are obviously more traditional paths of normative argument—whether on the grounds of ethics *or* neoclassical economic theory—that can and have been made against strict approaches to patent rights.[106] At the same time, if this Part does not simply reproduce arguments against a patent-based innovation system, it is for reasons other than just avoiding reinventing existing wheels. It is thus crucial for academics and policy makers to consider new exit strategies from the long-standing circle of traditional pro- and con- positions on

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[103] *E.g.*, Eric Budish, Benjamin N. Roin & Heidi Williams, *Do Fixed Patent Terms Distort Innovation? Evidence from Cancer Clinical Trials* (Nat'l Bureau Econ. Research, Working Paper No. 19430, 2013); Angus C. Chu, *The Welfare Cost of One-Size-Fits-All Patent Protection*, 35 J. ECON. DYNAMICS & CONTROL 876 (2011).

[104] The question of "optimal" patent length defies generalization across industries. Even in any given category the best approach to determining optimality is elusive. *See* C. Michael White, *Why a Seventeen Year Patent*, 38 J. PAT. OFF. SOC'Y 839 (1956); WILLIAM NORDHAUS, INVENTION, GROWTH AND WELFARE: A THEORETICAL TREATMENT OF TECHNOLOGICAL CHANGE (1969); Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 840 (1990); Andrew W. Horowitz & Edwin L.C. Lai, *Patent Length and the Rate of Innovation*, 37 INT'L ECON. REV. 785 (1996); Meir Perez Pugatch, *The International Political Economy of Intellectual Property Rights*, *in* NEW HORIZONS IN INTELLECTUAL PROPERTY 29–31 (2004).

[105] TRIPS Agreement, *supra* note 7, at art. 33.

[106] The most prominent figure to do so is Nobel Prize-winning economist, Joseph Stiglitz. Joseph E. Stiglitz, *Economic Foundations of Intellectual Property Rights*, 57 DUKE L.J. 1693 (2008); *see also, e.g.*, Richard T. Rapp & Richard P. Rozek, *Benefits and Costs of Intellectual Property Protection in Developing Countries*, 24 J. WORLD TRADE 75 (1990); Rebecca S. Eisenberg, *The Shifting Functional Balance of Patents and Drug Regulation*, 20 HEALTH AFF. 119 (2001); Aaron S. Kesselheim, Michael A. Fischer, & Jerry Avorn, *Extensions of Intellectual Property Rights and Delayed Adoption of Generic Drugs: Effects on Medicaid Spending*, 25 HEALTH AFF. 1637 (2006); MICHELE BOLDRIN & DAVID K. LEVINE, AGAINST INTELLECTUAL MONOPOLY (1st ed. 2008).

drug patents and public health. For doing so will not only help us make sense of the new pattern of conflict in developing countries around drug patents, but it will also help prevent the increasing level of debate about drug prices *in the developed world* from, itself, counterproductively becoming trapped in the same circle.

A. *Normative Arguments For and Against Patent Rights*

As conventionally understood, the rationales for patent rights are two-fold. One broad category of theories emphasizes the role of intellectual property as a means for rewarding creativity (taking into account both the labor and investment to create) that is considered as a good inherently worthy of reward.[107] While ostensibly free-standing, such views are difficult to separate from the second broad category of consequentialist justifications for patent rights that focus on the need to reward creativity (and the labor and investment going into it) in order to encourage technological innovation[108] and, thereby, the proliferation of the wider social good it engenders.[109] Insofar as the latter class of consequentialist bases for a strict approach to patent regime design is more specifically welfarist in nature,[110] the idea of the proliferating social good to which the incentivization of creativity is linked further permits justification to be articulated through the idiom of conventional economic theory. From the microeconomic standpoint, this entails emphasizing the

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[107] ROBERT P. MERGES, JUSTIFYING INTELLECTUAL PROPERTY 17–18 (1st ed. 2011).

[108] This is the case either if creativity is understood to be inherently reward worthy on "Kantian" lines (which tend to blur the deontological bases of property rights with a consequentialist one) or if deontology and consequentialism are, themselves, understood to be indistinct. For the equivocal nature of Kant's moral theory, see DAVID CUMMISKEY, KANTIAN CONSEQUENTIALISM (1996). On the inherent equivocality of the deontology/consequentialism distinction—albeit, in the context, of specifically "utilitarian" versions of consequentialism, and "rule" versus "act" versions of utilitarianism, see Gerald F. Gaus, *What is Deontology? Part One: Orthodox Views*, 35 J. VALUE INQUIRY 27, 28–29 (2001).

[109] For a more typical example of blurring these two bases of justification, see Gregory N. Mandel, *To Promote the Creative Process: Intellectual Property Law and Psychology of Creativity*, 86 NOTRE DAME L. REV. 1999 (2011).

[110] Of course, not all consequentialism is welfarist. *See* William W. Fisher & Talha Syed, *Global Justice in Healthcare: Developing Drugs for the Developing World*, 40 U.C. DAVIS L. REV. 581, 637 n.135, 638 n.140 (2006–2007).

possibility of a net welfare gain from erecting legal barriers to entry into a market by a firm's competitors. On this view, there is a long-term culture of innovation that can be expected to follow from assuring inventors an increased income that would otherwise be stymied by the free ridership of non-innovators on the ingenuity of others.[111] The overall benefit of mitigating the risks of R&D through patents is thus seen to outweigh the short-term cost (in lost consumer surplus) that may result from granting their holders exclusive rights.[112] In the context of international economic relations, much of the same reasoning is typically used to argue for the upward harmonization of country-level IPR standards, even despite the tendency for strict patent regimes to concentrate innovation in the developing world. The implicit assumption, in other words, is that longer-term economic welfare effects will eventually trickle down to the residents of the developing world.[113]

From the macroeconomic perspective, patent rights acquire a further significance when explaining economic growth. In this regard, patents are often thought to be significant because they help to sustain positive marginal returns to capital that create the additional positive spillovers (especially in a knowledge-based economy by furthering innovation, technology's learning-by-doing effects, and so on) necessary for growth, according to some economists.[114] This is because, unlike in the first wave of neoclassical growth theories of the kind pioneered by Robert Solow,[115] in so-called endogenous growth theory, technological

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[111] RONALD A. CASS & KEITH N. HYLTON, LAWS OF CREATION: PROPERTY RIGHTS IN THE WORLD OF IDEAS 179–81 (2013); Frank Easterbrook, *Intellectual Property Is Still Property*, 13 HARV. J. L. & PUB. POL'Y 108, 108–09 (1990).

[112] *See* NORDHAUS, *supra* note 104.

[113] FRANK MÜLLER-LANGER, GABLER, CREATING R&D INCENTIVES FOR MEDICINES FOR NEGLECTED DISEASES 99–100 (2009).

[114] Bart Verspagen, *Intellectual Property Rights in the World Economy, in* ECONOMICS, LAW AND INTELLECTUAL PROPERTY 489–518 (Ove Granstrand ed., 2003).

[115] Robert Solow, *A Contribution to the Theory of Economic Growth*, THE Q. J. OF ECON. 65, 70 (1956); Robert Solow, *Technical Change and the Aggregate Production Function*, 39 REV. ECON. & STAT. 312 (1957). For a recent restatement, see DARON ACEMOGLU, INTRODUCTION TO ECONOMIC GROWTH 56–69 (2008).

change is seen as more than just haphazard or accidental.[116] Instead, endogenous growth theorists envision technological change (including the type that one can argue is incentivized by patent rights) through investment in research and development to be part and parcel of economizing behavior itself as firms seek to overcome the effects of otherwise diminishing returns on their capital. Accordingly, insofar as a strong patent rights regime can be said to help facilitate technological change through driving R&D investment, it becomes a prerequisite to growth in its own right.[117]

While the above synopsis summarizes the main points of conventional economic theory's reformulation of the consequentialist basis for patent rights, it is not exhaustive. Besides the possibility that deadweight losses from the monopolistic tendencies[118] in pricing will be outweighed by the boon of a culture of innovation, others sometimes quote lesser economic reasons favoring strict patent rights. Especially in the pharmaceutical context, the effects of forcing information disclosure through the patent filing process can also produce benefits that redound to the economy more generally.[119] Some see the positive spillovers of technological innovation as necessary prerequisites to growth, while others emphasize that patents rationalize the process by which sequential innovations accumulate. Through setting the bargaining positions under which cooperation between first innovators and

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[116] For the canonical early formation, see Paul Romer, *Endogenous Technological Change*, 98 J. POL. ECON. 71 (1990). For a broader discussion of subsequent contributions by Romer and others, see GEORGE KORRES, TECHNICAL CHANGE AND ECONOMIC GROWTH: INSIDE THE KNOWLEDGE BASED ECONOMY 41–50 (2d ed. 2008).

[117] Verspagen, *supra* note 114, at 492–93.

[118] For a (purportedly) skeptical view about patents-as-outright monopolies, see Edmund W. Kitch, *Elementary and Persistent Errors in the Economic Analysis of Intellectual Property*, 53 VAND. L. REV. 1727 (2000).

[119] Roberto Mazzoleni & Richard R. Nelson, *The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate*, 27 RES. POL'Y 273, 278–79 (1998); *see also* STAFF OF COMM. ON THE JUDICIARY, 85TH CONG., STUDY OF THE S. COMM. ON PATENTS, TRADEMARKS, AND COPYRIGHTS (Comm. Print 1985).

those seeking to harness the positive externalities of their work proceeds, patents are thus said to promote additional efficiencies.[120]

It is not easy to square such potential advantages with the evident failure of the patent system in the context of infectious diseases. If it was, then the drugs-for-the-developing world controversy would not have gained as much attention.[121] Indeed, as William Fisher and Talha Syed note, the most apparent marks of this failure correspond less to a tradeoff between access and incentivization, and more to a failure to deliver either.[122]

First, some of the most effective existing therapies for treating infectious diseases are insulated by patent protection. This allows patent holders to price these therapies at a cost that the world's poor are not able to afford. Second, the new therapies that are greatly needed for treating these same infectious diseases are few and far between. As discussed earlier, firms are more focused on creating drugs that are functionally similar to lucrative equivalents already on the market or instead focused on creating new drugs for treating diseases that are most prevalent in high-income countries that generate more revenue.[123] Therefore, with regard to drugs for neglected diseases in low and middle-income countries, the market has proven incapable. There is no coordinating a proper overlap between the willingness (due to the underlying inability) of the afflicted to pay for existing therapies and the prices at which drug makers are allowed to set their willingness to accept payment. In turn, the market has been incapable of generating new therapies for infectious diseases that are already undersupplied.

We can further restate both halves of this two-sided failure for treating infectious diseases in terms of conventional economic theory. In the language of information economics, the failure to broaden access to communicable disease drugs corresponds to what Stiglitz calls the "static inefficiency" that IPRs create.[124] Strict patent

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[120] Suzanne Schotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. ECON. PERSP. 29 (1991).

[121] *See, e.g.*, sources cited *supra* notes 8, 48, and 57.

[122] Fisher & Syed, *supra* note 110, at 583.

[123] *Id.*

[124] Stiglitz, *supra* note 106.

rights exclude end users or competitors from capturing the additional utility value that their increased consumption of (medicinal) goods would otherwise make possible. This is because the main input to such goods is knowledge, the use of which carries no marginal cost. If consumers were permitted to consume more knowledge-based goods, or, if competitors to the patent holder were able to consume more knowledge for production, then more welfare would materialize. Accordingly, with knowledge-based goods, there is no *a priori* reason to think increasing output will lead to rising costs and increases in consumer prices. Indeed, there also is ample reason to think they would actually decrease due to more robust competition and market expansion.[125]

The apparent failure of IPR-inflated pricing to deliver innovation in the infectious disease drug context corresponds to what Stiglitz calls the problem of the "dynamic costs."[126] Even under the best-case scenario, as Stiglitz emphasizes, where patents do reward (and thus encourage) innovation, there is a fundamental disparity between marginal private and social returns. That is, the marginal social return from patents (when they do actually encourage innovation) lies in how they bring about innovation earlier than it otherwise would have materialized. Due to the scale and complexity of the research, especially for producing high technology goods, the innovation usually results from multiple research groups converging on the same breakthrough. The regular course of events, in other words, is clearly not the occurrence of some act of singular genius making the breakthrough.

Innovation instead usually takes place within, or based on, underlying foundational research, made possible by public funding or the public sector,[127] and is a matter of *when* and not *if*. However, patent-based innovation systems reward whoever gets there first in a way that fails to proportionally account for the benefit that newer

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[125] *Id.* at 1700.

[126] The "dynamic costs" making for a negative of patents in Stiglitz's eyes should be distinguished from his allusions to "dynamic incentives"—that is, incentivization—as a justification for patents. *Compare id.* at 1704, *with id.* at 1706.

[127] *See, e.g.*, MARIANA MAZZUCATO, THE ENTREPRENEURIAL STATE: DEBUNKING PUBLIC VS. PRIVATE SECTOR MYTHS (2013).

versions of the innovation will confer on society. That is, the patent system does not reward innovators based on the increment of social return resulting from innovation being brought to market earlier than it otherwise would have been; rather, it rewards the recipient of the right with a windfall gain comprising the entire value of the innovation.[128] Even if the pharmaceutical sector *was* providing a steady supply of new infectious disease drugs, patent protections on such hypothetical innovations would involve dynamic inefficiencies that could easily outweigh their apparent benefits.

B. *The Failure of the Market versus Market Failure*

The existing innovation system has demonstrated a notable inability to facilitate either the emergence of new communicable disease drugs or a widening of the availability of existing ones in the developing world. As a result, this would seem to give us good reason to hesitate before transposing the abstract dichotomy between access and incentivization (and the theoretical dilemma it portends) onto the NCD context. Mitigating against such hesitance, however, is the way that a failure to deliver either communicable disease drug access or incentivization can be detached from the problem of market failure—and certainly so as to deemphasize IPRs as its cause. "Market failure," in the technical sense, is the consequence of several underlying problems, such as imperfect information, preference structures that are mismatched in time, externalities, non-competitive markets, and public goods. Market failure is not a product of a failure to create equitable or otherwise ethically desirable results, but only of ones that fail to be "efficient" (whether on the more exacting standard of Pareto efficiency or some less exacting one like the Kaldor-Hicks variety).[129]

As suggested earlier, the misalignment between consumers and producers of communicable disease drugs *does* result from a non-competitive market and one that is substantially dictated by patents. The infectious disease drug market is thus characterized by goods

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[128] Stiglitz, *supra* note 106, at 1706–07.

[129] For a brief summary of these oft-discussed concepts, see Ken Cooper-Stephenson & Elaine Gibson, *Economic Analysis Substantive Inequality and Tort Law*, *in* TORT THEORY 137 (Ken Cooper-Stephenson & Elaine Gibson, eds., 1993).

with sale prices that do not correspond to their marginal cost of production. However, within the existing drugs-for-the-developing world debate, the implicit tendency has been to stop well short of casting such market imperfection as the cause of market failure. Instead, it becomes the consequence of rationally balancing one source of potential market failure with another that is particularly liable to affect pharmaceuticals as knowledge-based public goods.

Accordingly, a familiar train of suggestions ensues. Because there is no marginal cost associated with their key input of knowledge, public goods such as pharmaceuticals ordinarily would result in the greatest efficiency by being distributed for one and all to use freely.[130] However, this fails to account for the need to use past discoveries to generate new knowledge. As a result, the corrosive effects of free ridership are seen as a much greater concern for pharmaceuticals than for other knowledge-based public goods (which have actual or ostensible zero-marginal costs of use). Rather than two failed goals of the patent system (in the communicable disease drug context), access and incentivization instead end up as two poles of a seemingly imminent and zero-sum tradeoff.

Paradoxically, the concept of market failure ends up *adding to* rather than *taking away from* the case for strict IP regime design. This is especially so when we consider that law and policy concepts are deployed not only in specialist literature, but also more importantly as part of ordinary language sound bites in the public sphere. In terms of its rhetorical structure, the existing drugs-for-the-developing world debate has meant no sooner is the question of market failure raised than it is made to recede. In its place, the key question instead becomes one stated in terms of how we should trade off aims that are ostensibly different in kind: whether of the short- versus long-term, the "ethical" versus the "economic," or, in cannibalizing Stiglitz's critique of strong IPR, the "static inefficiencies" of patents versus their "dynamic incentives."[131]

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[130] Stiglitz, *supra* note 106, at 1700.

[131] *See generally* Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. INT'L ECON. L. 849 (2002); James Huebner, *Moral Psychology and the Intuition that Pharmaceutical Companies Have a 'Special' Obligation to Society*, 122 J. BUS. ETHICS 501 (2014); Sara Parker-Lue, Michael

Even when the existing infectious disease drug market is imagined to reinstate the supposedly acute normative dilemma between access and incentivization, all of the same objections remain that lean against strong IPR. It is thus not clear that drug patents have been successful in promoting innovation, despite the fact that pharmaceuticals are often said to be one of the best examples of strong IPR at work.[132] Additionally, what innovation does occur in drug development is financed largely through public funding, especially for the foundational research on which the products of privatized end-stage invention are parasitic.[133] Then there also remains the issue of how the revenues that are generated by allowing producers to sell patented compounds above their marginal costs are actually used. As noted earlier, rather than for the purposes of financing R&D, these funds are now routinely and increasingly apportioned to ever-expanding budgets that firms devote to marketing and advertising.[134]

Santoro & Greg Koski, *The Ethics and Economics of Pharmaceutical Pricing*, 55 ANN. REV. PHARMACOLOGY & TOXICOLOGY 191 (2015); *The New Drugs War,* THE ECONOMIST (Jan. 4, 2014), https://www.economist.com/news/leaders/21592619-patents-drugs-are-interests-sick-well-industry-protection-should-not.

[132] For the case favoring the innovation-promoting effects of drug patents, see Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. INT'L ECON. L. 849 (2002). For the skeptical view, see MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES (1st ed. 2004); Michael Boldrin & David Levine, *The Case Against Patents*, 27 J. ECON. PERSP. 3 (2013); Carlos Maria Correa, *Ownership of Knowledge: The Role of Patents in Pharmaceutical R&D*, 82 BULL. WORLD HEALTH ORG. 784 (2004); Donald Light & Joel Lexchin, *Pharmaceutical Research and Development: What Do We Get for All that Money*, 344 BMJ (2012).

[133] *See* G. Steven McMillan, Francis Narin & David L. Deeds, *An Analysis of the Critical Role of Public Science in Innovation: The Case of Biotechnology*, 29 RESEARCH POL'Y 1 (2000); Ammon J. Salter & Ben R. Martin, *The Economic Benefits of Publicly Funded Basic Research: A Critical Review*, 30 RESEARCH POL'Y 509 (2001); Hamilton Moses III et al., *Financial Anatomy of Biomedical Research*, 294 J. AMER. MED. ASS. 1333 (2005); Bhaven N. Sampet, *The Impact of Publicly Funded Biomedical and Health Research: A Review*, *in* NATIONAL ACADEMIES OF SCIENCE, MEASURING THE IMPACTS OF FEDERAL INVESTMENTS IN RESEARCH: A WORKSHOP SUMMARY 153 (2011); MAZZUCATTO, *supra* note 127.

[134] *See* James Love, *Pharmaceutical Research Development and the Patent System*, 35 INT'L J. HEALTH SERV. 257 (2005); Joseph E. Stiglitz & Arjun

Regardless of these objections, in the absence of any *a priori* way of definitively calculating how to make the relevant tradeoff, the familiar metaphor of balancing implies that the difficulty of the choice lies in sacrificing present "do-gooding" for a more sober-minded view of the future. On this view, a strict IP regime becomes the lesser of two evils because it ultimately preserves the ongoing existence of the market and the progress it is purported to have made possible in the first place. Paradoxically, *the more* extreme the failure of the market in ensuring pharmaceutical access and incentivization in the infectious disease drug context is, *the less* strictly is the approach to patents because of the problem of *market failure*, in the technical sense of economic theory. On the contrary, the more extreme the *market's failure* has been, the more government interference with private rights has been seen as the real problem. Ultimately, strict approaches to patent rights and the upward harmonization of national IP regime design becomes presumptuously market-strengthening, notwithstanding the way it openly undermines competitive market structures.

By assuming that the developing world is plagued by communicable disease alone, an inverse proportionality is created between the perceived relevance of the technical problem of market failure and that of the market's practical failure to elicit either pharmaceutical access or incentivization. Indeed, the very existence of this inverse proportionality further heightens the sense that the real problem is forgoing "ethics" for "economics." In other words, once the upward harmonization of national IP regime design is seen to result from a necessary tradeoff between accepting imperfection in the competitive structure of the market in the present and avoiding greater market disruption due to the problem of public goods in the future, the economics of market failure is even more clearly absolved of relevance. In turn, the purported fact that the majority of the developing world's inhabitants are simply outside the market creates greater concern. This is because these inhabitants are viewed less as consumers whose demand the market has *failed* to equilibrate

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Jayadev, *Medicines for Tomorrow: Some Alternative Proposals to Promote Socially Beneficial Research and Development in Pharmaceuticals*, 7 J. GENERIC MED. 217, 219 (2010).

with the corresponding supply than they are as a class of needy or (potentially) afflicted. Therefore, the dichotomy between economics and ethics ends up being entrenched. Increasing pharmaceutical access depends, at best, only on a stance rooted in a morality of deontic empathy or utilitarian prudence—and not any justifiable compunction born from economics' higher rationality.

Needless to say, there are many problems with distinctly separating the economic dimension from the ethical dimension of strict approaches to patents and the upward harmonization of national IPR regime design. First and foremost, it reifies the market.[135] To categorically distinguish the two thus ends up naturalizing one highly contingent way in which to arrange certain aspects of the market's institutional design; namely, that which follows from strict approaches to IPR. Whether seen as necessary or counterproductive—by their supporters and detractors, respectively—alternative institutional arrangements appear as if they can follow only from imposing outside logics onto the design of the rule regime that economics would otherwise clearly mandate. To dichotomize the logics that factor into questions about national IP regime design also then exacerbates the tendency for the drugs-for-the-developing world debate to become a proxy for the larger debate on free trade to which it need not be related at all. For that debate, too, has been rhetorically premised on a categorical distinction between the "economic" and the "ethical" issues raised by globalization. In turn, departures from strict IPR frameworks of the kind that have been pushed through free trade agreements in the post-Cold War come to be reflexively delegitimized as examples of protectionist antipathy to a true ethos of market freedom.

C. *Re-Contextualizing the Access-Incentivization Dilemma in Light of the Crisis/Economics of NCDs*

The circumstances that bring together those who produce drugs for infectious diseases and those who need these drugs have thus been made to seem extremely fragile. On the one hand, there is a market within which consumers are so devoid of purchasing power

[135] For a succinct literature summary, see Fisher & Syed, *supra* note 110, at 257.

that they make, in effect, for *no* market at all. With such individuals becoming more so a collection of the needy than any aggregate source of demand, their predicament attenuates any sense that the real problem is one of market failure. On the other hand, there is no significant class of persons afflicted by "third world" ailments in rich countries. Consequently, even notwithstanding the obvious and often severe economic stratifications within high-income countries, low and middle-income countries are the *only* market for such drugs. In the end, it becomes more implausible to regard the developing world as a realm in which companies should be expected to function out of the goodness of their hearts.

As different as these two circumstances may appear on the surface, however, underneath they evoke a surprisingly resilient figure of the multinational pharmaceutical firm. This is because the multinational is portrayed as being squeezed on all sides. On one side, it is threatened by the public's perception that the firms profit off of the sick and dying bodies of the poor. On the other side, it faces the hard facts that there is little reason to manufacture—let alone research and develop alternatives for—the types of drugs needed for those in low and middle-income countries. The portrait of the pharmaceutical industry as a victim besieged on all sides effectively suggests that the prices for infectious disease drugs, absent patents, would have to be entirely non-remunerative. In turn, any denial of the firm's ability to avail itself of patent protections ends up becoming the real interference with the market, and also one that is both insensible *and* unfair.

The sophisticated observer may well know that there are more specific empirical considerations upon which the veracity of these suggestions—leading back to an intractable access-incentivization dilemma—actually depends. Yet in the public sphere, the recurrent starting point for the drugs-for-the-developing world debate is the multinational pharmaceutical firm, which is seen as the inheritor of an impossible role. On the one hand, the firm is seen as being left to stand watch over the economic incentives necessary to make drug development possible. On the other, it is then scorned for ethical villainy. Not surprisingly, we consequently often hear about the widely quoted, but much less interrogated, price tag of $800 million—or, since the latest update, now $2.6 billion—that the

development of a single new compound is purported to cost.[136] Even within economically fluent legal literature, there is a substantial tendency to start from the same kinds of observation—this is partly because of the highly porous boundary between specialist scholarship and the discourse of the public sphere.

Against such a backdrop, it is unsurprising that the means for making essential medicines for infectious diseases more readily available in the developing world are typically framed as exceptions to a default of strict patent rights. Such potential exceptions include mandatory licensing agreements; segmented markets through tiered pricing; lower retail prices through parallel importation; government-declared national and public health emergency as a basis for licensing; so-called true equity pricing; and more robust competition through assorted ways of building up the generic drug industries.[137]

Often discussed in the WTO context as so-called TRIPS-flexibilities, these measures have not all been equally accepted, much less operationalized. Even so, characterizing them as exceptions from a norm of strict IPR rather than paths to a different norm altogether has always been due to the constraints of political reality as much as logical necessity. For example, the need for national emergency licenses is bound to seem exceptional only if it is imaginatively surrounded by the assumption of an ostensibly non-context dependent zero-sum tradeoff, demanding that we prioritize hypothetical incentivization over access. Yet once we begin to reckon with the normative aims of access and incentivization from the standpoint of the developing world's NCD crisis, national emergency licensing just as well may exemplify the arbitrary nature of treating upward harmonization of national IP regime design as the preferred norm. This is because unlike with communicable diseases, the global burden of which are concentrated in areas with the economically least remunerative markets, NCDs and the cost-

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[136] *See* DiMasi, *supra* note 8.

[137] Dianne Nicol & Olasupo Owoeye, *Using TRIPS Flexibilities to Facilitate Access to Medicines*, 91 BULLETIN OF THE WORLD HEALTH ORGANIZATION [WHO] (Apr. 18, 2013), http://www.who.int/bulletin/volumes/91/7/12-115865/en/.

amortizing supracompetitive profits they provide from developed world markets are distributed more evenly across all country groups.

If the crucial importance of this fact has not been at the forefront of academic and policy debate in the developed world, there is little doubt about its becoming so in the developing world. Indeed, the new pattern of conflict over drug patents and the TRIPS that has emerged since 2010testifies to that. As the global share of NCD burden absorbed by developing countries increases, controversies over patents will increasingly call the theoretical good sense of upward harmonization/strict IPR itself into question. This is a matter the article returns to in the new pattern of conflict it documents between developing countries and multinational pharmaceutical firms in Part VI.

Even if the marketization of low and middle-income country demand for NCD drugs becomes constrained in the future, existing levels of cost-amortizing supracompetitive profits should remain intact. It is important to remember that current returns are evidently more than sufficient to sustain the high levels of profitability the multinational pharmaceutical sector reports.[138] Nor is there any reason to expect that firms will suddenly siphon existing returns in order to escalate the subsidy they provide to R&D for new infectious disease drugs.

To say only this much is to misstate the present state of affairs. Rather than remaining at a standstill, multinationals will commodify at least part of the growing number of developing world inhabitants who will be afflicted with "rich country" diseases in the years to come. Dominant firms will thus be positioned to capture a new and distinct source of expanding profits as the well-off in the developing world increasingly consume not only more animal protein and automobiles, but also more therapies for the illnesses that such

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[138] *See, e.g.*, Richard Anderson, *Pharmaceutical Industry Gets High on Fat Profits*, BBC NEWS (Nov. 6, 2014), http://www.bbc.com/news/business-28212223; Liyan Chen, *The Most Profitable Industries in 2016*, FORBES (Dec. 21, 2015), http://www.forbes.com/sites/liyanchen/2015/12/21/the-most-profitable-industries-in-2016/#3ee997ae7a8b; Linda A. Johnson, *Merck Profit Soars on New Drugs, Expects Better 2017*, BOSTON GLOBE (Feb. 3, 2017), https://www.bostonglobe.com/business/2017/02/02/merck-profit-soars-new-drugs-expects-better/Z1JLDOOA85Kav1YX8JlEKJ/story.html.

lifestyles bring. Even supposing that firms reap no additional profits from such novel revenue sources, there is still no reason to expect any drastic worsening in the highly lucrative status quo that the multinational pharmaceutical sector presently enjoys. If anything, it is only reasonable to expect the opposite given that the NCD crisis will expand and bring new market opportunities not only in the developing world but also in the developed world itself.

What if the multinational pharmaceutical sector ends up facing the even more unlikely eventuality of having to sell NCD drugs to developing world consumers only at marginal cost? There is still little reason to expect any deterioration of the existing situation of windfall profits—assuming that high-income country markets remained quarantined from arbitrage opportunities.[139] Suffice to say, the industry would hardly fail to mobilize its political power at home to maintain (and expand) legal restrictions that already largely disbar intermediaries from importing developing country versions of drugs back into their home markets.[140] Indeed, even if this extreme unlikelihood came to fruition, it would lead to a deterioration in the industry's bottom line only if arbitrage pushed the original supplier's ability to sell in the home market down to the same minimum. However, this defies both logic and existing reality. Ultimately, a future in which being forced to sell only at marginal cost in the developing world leads to the pharmaceutical sector's current levels of high profitability deteriorating—or even staying the same—rather than expanding with the growing global NCD crisis is highly unlikely.

The various qualifications outlined above are especially worth noting as we turn to the most careful of existing attempts to reckon with the access-incentivization dilemma in light of the developing world's emerging NCD crisis. In his article on the topic, Keith Outterson distinguishes "neglected diseases" of the kind most readily associated with health crisis in low and middle-income

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[139] Of course, even if arbitrage increased, it is not clear that it would or does have the effects the pharmaceutical sector warns. *See generally* Keith Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y L. & ETHICS 193 (2005).

[140] *Id*.

countries from what he calls "global diseases."[141] Because global diseases affect rich and poor-country inhabitants alike, but the poor disproportionately, Outterson advocates that these conditions should be addressed through a system of what he calls "patent buy-outs."[142]

Under such a system, only inhabitants of high-income countries would bear the cost of pharmaceutical patent rents.[143] All patented drugs would then be offered to the other 84% of the world's population at generic prices.[144] This, Outterson argues, would create widespread public health gains by making medicines for all diseases more affordable in the developing world. At the same time, it would bring only a very slight decrease in global research and development cost recovery: as he notes, the more than 80% of patent-based cash flow undergirding such spending that now comes from sales within Organization for Economic Cooperation and Development countries would remain untouched.[145] Indeed, it is in order to make up for even this slight deficit in the funds available for R&D spending that Outterson proposes the mechanism of patent buy-outs in the first place.[146] Accordingly, its explicit purpose is to "[restore] to the companies" lost revenues from the inability to sell above marginal cost in developing world markets.[147]

Outterson's thoughtful proposal is notable for a number of reasons. Most of all, he is one of the few who have sought to address the drugs-for-the-developing world debate on a comprehensive basis by asking how to address both communicable and non-communicable diseases. At the same time, the proposal is notable because it is premised on the assumption that even a minimal departure from the status quo guaranteeing high profits to

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[141] Keith Outterson, *Patent Buy-Outs for Global Disease Innovations for Low- and Middle-Income Countries*, 32 AMER J.L. & MED. 159, 161 (2006) ("*Global diseases* are conditions which affect both rich and poor countries, but disproportionately affect the poor.").

[142] *Id.*

[143] *Id.* at 160.

[144] *Id*. at 171 (indicating that Outterson means marginal cost pricing).

[145] *Id.*; *see also* Outterson, *supra* note 139, at 248.

[146] Outterson, *supra* note 141, at 160.

[147] *Id.* Given the difficulty of knowing the true costs pharmaceutical firms bear, Outterson runs through various scenarios about how his buy-out price might be calculated. *Id*. at 173.

pharmaceutical multinationals would be unacceptable. This is implicit in the very idea of a buy-out mechanism that seeks to restore existing rents rather than some other negative, zero, or otherwise more constrained positive value above the margin.

In this respect, one might say that what the proposal purports to give with one hand in terms of practical feasibility for addressing the ill effects of the patent system it takes away with the other. For it would still leave intact the normative stalemate that has emerged from the past two decades of debate based on the implicit context of a developing world plagued by non-remunerative "third world" diseases alone. Indeed, we can further illuminate this point by considering the practical complications that would surely await any patent buy-out mechanism of Outterson's kind.

Chief among these is the dual complication of (1) over-including developing world elites—who would otherwise be able to pay full prices—within the system of generic cost provisioning and (2) under-including those in the developed world who could not.[148] For his own part, Outterson does acknowledge that over-inclusion — especially of the millions who purportedly rank among the middle classes in places like China, India, and Brazil—would be particularly likely to attract opposition. However, the proposal underplays this admission by too hastily imagining that the inclusivity problem would find its own solution.[149] Thus, on the one hand, Outterson suggests that under-inclusion could fix itself directly, given the very purpose of the buy-out mechanism.[150] That is, the mechanism would naturally require larger transfers to pharmaceutical firms as the magnitude of lost rents increased. On the other hand, he suggests that under-inclusion might instead fix itself indirectly. In this case, the problem would prompt pharmaceutical companies to more vociferously pursue tiered pricing in developing country markets through brand campaigns and new restrictions on arbitrage.[151]

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[148] *Id*. at 172.
[149] *Id.* at 172–73.
[150] *Id*.
[151] *Id*.

Believing in the likelihood of such self-executing solutions, however, portrays an attitude that is too sanguine about the ease with which under-inclusion would abate. Even a buy-out mechanism designed to keep the magnitude of existing returns to the multinational pharmaceutical sector untouched would thus hardly be any more practically feasible than whatever other solutions we might imagine. There are at least five more specific reasons why this is so.

The first concerns the mechanism leading to the indirect fix for under-inclusion. For that mechanism could just as easily undermine the efficacy of the buy-out system overall. Building momentum for market segmentation to enable higher price tiers that could more easily make up for lost rents thus seems to be at sharp odds with fostering a market ethos receptive to making generics available at marginal cost. Likewise, insofar as the same momentum would lead to more intensive restrictions on arbitrage, its logic would again work against facilitating a culture of availability at marginal cost.

Second, it is unclear why firms would accept recovery of lost rents from the elite stratum of developing world inhabitants alone. A highly contentious round of bargaining seems just as likely, and it is easy to imagine that it would aim for a costlier system based on a gradation of proportional buy-outs for what firms would argue were foregone revenues from additional down-market segments of developing world consumers. Given the visibility of their middle classes, Brazil, India, and China would become major flashpoints and possibly derail the whole buy-out system. This is especially because the proposal already assumes that special arrangements would be needed for these same countries to foot the bill for the buy-outs directly from their own national budgets. If we cannot practically expect the United States, European Union, or the United Nations to finance buying out lost rents from these countries, why should we imagine that the pharmaceutical sector would be content losing more rather than less of those rents?[152] Of course, this is assuming that getting countries like Brazil, India, and China to buy out even just the equivalent of rents from their middle classes would be possible in the first place.

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[152] *Id.*

Third, and even more troubling, the sizes of the developing world's middle classes are difficult to estimate with certainty. This is compounded by the fact that, at least in conventional discussion, those classes are assumed to be rapidly increasing. If this was so, the multinational pharmaceutical sector would have even (more) reason to support a buy-out system of any kind. After all, the alternative would be a status quo in which firms could continue extracting at least their current rents from developing world markets directly. Especially with an expanding pool of such rents to anticipate, is a buy-out system really a more feasible solution than moving away from a norm of strict patent rights altogether?

Fourth, and related, is the following question: if support for a buy-out mechanism (to incentivize ongoing R&D) is less likely than the proposal makes it seem, and if the patent system is as detrimental to access as the proposal assumes, what confidence can we have in the political reality it is built upon? This fourth problem is closely related to the fifth and last problem.

This last problem is, namely, that it seems that actual events in the developing world are already reconstituting the sense of what is politically feasible. In this respect, the horizon of possibility seems to be moving in a very different direction from that which the patent buy-out mechanism assumes, as developing countries shift toward strategically contesting patents for NCD drugs. This pattern of conflict obviously cannot be completely divorced from the long history of controversy around various infectious disease drugs going back to the late 1990s.[153] However, even as it builds on what came before, there is clearly a departure.

VI. BREAKING WITH STRICT PATENT RIGHTS ON NCD DRUGS

As the Gleevec controversy in India suggested, well before the current rise of skepticism about free trade liberalization, there has emerged a renewed push for questioning strict IPR in the developing world. This push back against strict IPR, however, has come largely from civil society, heterodox economics, health equity, and

[153] *See generally* HULME, *supra* note 50.

responsible government perspectives rather than from party politics. In both theory and fact, it thus adds to the reasons why the crisis of NCDs is becoming the key issue that should encourage policymakers to assess the rules governing our global innovation system moving forward.

While in the last half-decade developing countries have used many strategies to contest patents on NCDs—and, by extension, the architecture of TRIPS-based IPR regime design—it is beyond the scope of this paper to describe them all. Instead, in this section, an illustrative approach to two main types of contest is discussed. Continuing the discussion of the *Novartis* decision in India, the first involves further examples of developing countries that are effectively heightening the bar for patentability in the face of modifications to existing compounds.[154] The second involves contests over NCD drugs rooted in the crucial mechanism for breaking with strict patent rights known as compulsory licensing.[155]

A. *Measures Heightening the Bar for Patentability (of Modifications)*

1. *India and Tykerb*

Soon after the Indian Supreme Court's decision in the Gleevec case, India's IPAB revoked the patent on another prominent cancer drug known as lapatinib ditosylate. Sold by GlaxoSmithKline (GSK) under the name Tykerb, the drug is another tyrosine kinase inhibitor.[156] It was initially approved for use in the U.S. in 2007.[157]

In June 2008, the Kolkata office of the Controller of Patents issued GSK two patents, one for lapatinib and one for its ditosylate salt.[158] Five years later, shortly after the Gleevec case was resolved,

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[154] For a summary of the various examples detailed in Part VI.A, see *supra* Table 1.

[155] For a summary of the various examples detailed in Part VI.B, see *supra* Table 2.

[156] *See* Qin Ryan et al., *FDA Drug Approval Summary*, 13(10) ONCOLOGIST 1114 (2008). The initial approval was a part of a combination therapy with Roche's xeloda. *Id.*

[157] *Id.*

[158] *See* INTELL. PROP. APP. BOARD, ORDER NO. 161 of 2013 (July 27, 2013) (India).

in 2013 the IPAB issued two distinct decisions on the Tykerb controversy. Lapatinib itself was deemed non-obvious and thus a true qualifying invention protected from competition until 2019.[159] However, the IPAB revoked the patent for the salt form of the drug on two grounds. First, it held that GSK failed to meet the statutory requirement for non-obviousness under the Patents Act. Second, it found that GSK's application fell afoul of Section 3(d).[160] With the *Novartis* decision still fresh, the Section 3(d) rejection was solely because the IPAB revoked GSK's patent. As the IPAB declared, it "need not examine any further" claims made by the petitioner, but would address the "obviousness . . . issue since . . . [it was] important."[161] With the Tykerb controversy, it is not by accident that the *Novartis* decision's approach to defining Section 3(d)'s heightened standard of patentability for modifications was cemented in the context of another prominent NCD drug.[162]

2. *India and Abraxane*

The third prominent recent case involving a heightened bar of patentability for NCD therapies in India involved another cancer drug named paclitaxel, a mitotic inhibitor. Paclitaxel was approved by the Food and Drug Administration (FDA) in the early 1990s to treat breast and ovarian cancers.[163] Over the years, it has grown to include treatment for lung and pancreatic cancer as well.[164]

Paclitaxel was originally commercialized by Bristol-Myers Squibb under the brand name Taxol.[165] Subsequently, the biotechnology company Abraxis BioScience (later acquired by Celgene), modified the drug by binding it to the protein albumin.[166] This allows the drug to be administered intravenously in injectable

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[159] *See id.*

[160] *Id*. at para. 50.

[161] *Id*.

[162] *Id*. at para. 49. The Intellectual Property Appellate Board also borrowed the Court's meaning of efficacy as therapeutic efficacy. *Id.*

[163] *See* In the Matter of Application No. 2899/DELNP/2005 (Off. Controller Gen. Pat. Designs & Trademarks 2014) (India), http://ipindiaservices.gov.in/decision/2899-DELNP-2005-6374/2899%20DELNP%202005%20Decision.pdf.

[164] *See id.*

[165] *Id.* at para. 17.1.

[166] *Id.* at para. 13.1.

form. The albumin-bound modified version was called Abraxane, and Abraxis Bioscience filed for a patent on it in India in 2005.[167] In 2009, India's Patent Office heard a motion for pre-grant opposition from the generics manufacturer Natco Pharma, claiming that Abraxane lacked an inventive step.[168] Concurring with Natco's assertions, the IPO's Assistant Controller rejected Abraxis BioScience's application on Section 3(d) grounds.[169] In so doing, it cited the applicant's inability to show that the albumin-bound form of paclitaxel had enhanced efficacy, understood to mean therapeutic efficacy as outlined in the *Novartis* decision.[170] On appeal to the IPAB, the original decision was remanded back to the IPO to be considered anew.[171] At the same time, Natco issued updated claims in opposition.[172] In June 2014, the Indian Patent Office rejected Abraxane's patent application once more.[173]

3. *India and Januvia*

We now turn to a controversy surrounding diabetic drugs in India. While still not fully settled, a major battle has been ongoing over Merck's Januvia, a widely-used type-2 diabetes medicine. Januvia is the phosphate salt form of sitagliptin, a compound that increases insulin levels in the body, thereby lowering blood glucose.[174] Januvia was approved in the U.S. by the FDA in 2006, and by 2007, modified preparations appeared on the market, most notably Janumet.[175] In creating Janumet, Merck combined Januvia with another diabetic drug called metformin, which was already a generic drug in the U.S.[176] This combination provided patients with

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[167] *Id.* at para. 1.
[168] *Id.* at para. 12.
[169] *Id.* at para. 18.
[170] *Id.* at para. 16.9.
[171] *Id.* at para. 4.
[172] *Id.* at para. 3.
[173] *Id.* at para. 18.
[174] *Sitagliptin*, MEDICINEPLUS (last updated Oct. 24, 2017), http://www.nlm.nih.gov/medlineplus/druginfo/meds/a606023.html.
[175] Aaron Smith, *FDA Approves Merck Diabetes Drug*, CNN (Oct. 17, 2006, 1:29 PM), http://money.cnn.com/2006/10/17/news/companies/merck/index.htm.
[176] Mike Benson, *Januvia and Janumet: Merck & Co.'s Blockbuster Diabetes Products*, MARKET REALIST (Feb. 22, 2017, 1:02 AM),

one pill (Janumet) containing two diabetes drugs (Januvia as the modified salt form of sitagliptin and metformin).[177]

Merck had originally secured patents on sitagliptin in India in 2007.[178] However, after applying for new protections for Januvia (the modified phosphate salt form of sitagliptin), the IPO rejected granting Merck additional rights upon hearing a motion for pre-grant opposition brought by the Indian company Glenmark Pharmaceuticals.[179]

After the IPO's ruling in April of 2013, Glenmark then released generic versions of both Januvia and Janumet under the names Zita and Zitamet, respectively.[180] Merck immediately filed suit in the Delhi High Court, requesting an interim injunction to restrain Glenmark from infringing on its patents.[181] In defense of its actions, Glenmark argued that it was not infringing on Merck's original sitagliptin patent.[182] Rather, Glenmark argued that Zita and Zitamet were generic versions of the distinct but unpatented entity comprised of sitagliptin's phosphate salt (Januvia and Janumet).[183] Glenmark thus claimed that there was no protected entity that Zita or Zitamet could be infringing upon.[184] In response, Merck argued

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http://marketrealist.com/2017/02/januvia-and-janumet-mercks-blockbuster-diabetes-products-2/.

[177] *Id.*

[178] C.H. Unnikrishnan, *First Patent War in India's Diabetes Market Gets Intense*, LIVEMINT (Apr. 7, 2013, 10:33 PM), http://www.livemint.com/Companies/XMrH6IgwgtO164uNZKIFdL/First-patent-war-in-Indias-diabetes-market-gets-intense.html.

[179] *See* Gopakumar G. Nair, Andreya Fernandes & Karthika Nair, *Landmark Pharma Patent Jurisprudence in India*, 19 J. INTELL. PROP. RTS. 79, 84–85 (2014).

[180] *See* Rupali Mukherjeel, *Patent War Over Drugs Goes Chronic*, TIMES OF INDIA (Apr. 1, 2013, 4:28 AM), https://timesofindia.indiatimes.com/business/india-business/Patent-war-over-drugs-goes-chronic/articleshow/19315419.cms.

[181] For the initial decision of the Delhi High Court, see Merck Sharp & Dohme Corp. v. Glenmark Pharmaceuticals, Ltd., Unreported Judgments 2015 (Del.) (India), http://lobis.nic.in/ddir/dhc/AKP/judgement/07-10-2015/AKP07102015S5862013.pdf.

[182] *Id.* at paras. 8–9.

[183] *Id.*

[184] *Id*. at para. 10.

that its phosphate salt was not an entity distinct from sitagliptin.[185] Merck even went so far as to use Section 3(d) of the Patents Act to claim the phosphate salt form of sitagliptin was nothing more than a derivative.[186]

The Delhi High Court ultimately denied Merck's request for an interim injunction, largely endorsing Glenmark's reasoning.[187] However, on appeal in March 2015, the decision was reversed.[188] While the ultimate outcome of the Januvia controversy waits to be determined,[189] the proceedings to date illustrate that conflict over Section 3(d) is not limited to cancer drugs. For example, a similar controversy is currently raging between various Indian generics companies and Novartis over Vildagliptin, another diabetic drug.[190]

The Januvia conflict in India once more illustrates the way in which Section 3(d) has become entangled within its broader IP regime. It was thus Section 3(d) that became the IPO's basis for denying Merck a patent on the phosphate salt of sitagliptin.[191]

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[185] *Id*. at para. 12.

[186] *Id*. at para. 13.

[187] *See id*. at para. 26. Drawing on the *Novartis* decision, the Court turned its Section 3(d) implications on their heads, arguing that it was up to Merck to show that the phosphate form of sitagliptin was indistinct from the non-phosphate form and failed to enhance therapeutic efficacy. *See id.* at para. 74.

[188] *See* Merck Sharp & Dohme Corp. v. Glenmark Pharmaceuticals, Ltd., Unreported Judgments 2015 (Del.) (India), http://lobis.nic.in/ddir/dhc/SRB/judgement/06-07-2015/SRB20032015FAOOS1902013.pdf.

[189] *See* Shreeja Sen, *SC Stays Delhi HC Order Restraining Glenmark from Making Anti-Diabetes Drug*, LIVEMINT (Mar. 25, 2015, 3:06 PM), http://www.livemint.com/Companies/H0TjAmE0SMQaQQ3lEqfebP/SC-stays-Delhi-HC-order-restraining-Glenmark-from-making-ant.html. Only two days after the Delhi High Court's appeal decision, its grant of interim injunction against Glenmark was staid by India's Supreme Court. *Id.*

[190] Apoorva, *Court Grants Novartis Temporary Injunction Against Ranbaxy*, LIVEMINT (Sept. 9, 2014, 12:55 AM), http://www.livemint.com/Industry/HiulunjJR3DSHvftkPonfK/Courtgrants-Novartis-temporary-injunction-against-Ranbaxy.html. The patent on Vildagliptin, sold in India under the brand name Galvus, expires at the end of 2019. *Id.* In September 2014, the Delhi High Court granted Novartis's request for a temporary injunction against Indian drug maker Ranbaxy Laboratories to prevent it from selling a generic version of the drug. *Id.*

[191] Merck Sharp & Dohme Corp. v. Glenmark Pharmaceuticals, Ltd., Unreported Judgments 2015 (Del.) (India), at para. 74, http://lobis.nic.in/ddir/dhc/AKP/judgement/07-10-2015/AKP07102015S5862013.pdf.

Likewise, Glenmark additionally invoked Section 3(d) in justifying its choice to issue generic forms of Januvia and Janumet.[192] Indeed, the provision was even cited by Merck to oppose Glenmark's actions.[193]

4. *The Philippines and Lipitor (and Lyrica)*

The importance of the Indian Supreme Court's *Novartis* decision has not been confined to India alone.[194] Soon after its initial passage, Section 3(d) began to inspire other developing countries to institute similar provisions. In 2008, through the Universally Accessible Cheaper and Quality Medicines Act (R.A. 9502), the Philippines amended its eleven-year-old patent code, which was known as Republic Act No. 8293 (R.A. 8293),[195] by inserting language very similar to Section 3(d) with two different amendments (Rule 8, Section 1 dealing with "Non-Patentable Inventions" and Rule 8, Section 2 dealing with "Inventive Step"[196]).

With these amendments, the Philippines Congress codified the amended Indian Patents Act's heightened bar for patentability as construed in the *Novartis* decision as part of its own IPR regime. Specifically, the amended Section 26.2 of Republic Act 8293 elaborates new rules for a product to qualify as an invention;[197] the

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[192] *Id.*

[193] *Id.* at para. 13. Merck's logic is especially worth considering. For if by its own admission, Januvia was nothing more than a derivative, why was the company trying to patent the drug to begin with? Adjusting to the new norm of triumphant Section 3(d), Merck was left to explain its original attempt at patenting the salt as a misguided error. *See id.* at 17.

[194] *See* Rajarshi Banerjee, *The Success of, and Response to, India's Law Against Patent Layering*, 54 HARV. INT'L. L.J. 204, 206–07 (2013).

[195] An Act Prescribing the Intellectual Property Code and Establishing the Intellectual Property Office, Providing for its Powers and Functions, and for Other Purposes, Rep. Act No. 8293 (1997) (Phil.), http://www.wipo.int /wipolex/en/text.jsp?file_id=129343. The act was passed to bring the Philippines into TRIPS-compliance. *See id.*

[196] *See* An Act Providing for Cheaper and Quality Medicines, Amending for the Purpose Republic Act No. 8293, or the Intellectual Property Code, Republic Act No. 6675, or the Generics Act of 1998, and Republic Act No. 5921, or the Pharmacy Law, and for Other Purposes, Rep. Act No. 9502 (2008) (Phil.), http://www.wipo.int/wipolex/en/text.jsp?file_id=162755.

[197] Under a heading entitled "Inventive Step," Section 26.2 of the Philippines amended patent code now reads as follows:

amended Section 22 also outlines more stringent criteria for patentability.[198] Indeed, immediately after President Gloria Arroyo signed the amendments into law, controversy erupted in the country over Pfizer's enormously important Lipitor.[199]

The branded version of atorvastatin, Lipitor, is a lipid-lowering agent used to treat high cholesterol. The drug is a polymorph salt form of atorvastatin.[200] By 2011, Lipitor was already history's best-selling drug.[201] That same year, however, Pfizer's U.S. patent was set to expire, with its Philippines patent to follow suit soon after in 2012.[202] As a modified salt form, the compound underlying Lipitor became a repeated source of conflict throughout the world—from

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> In the case of drugs and medicines, there is no inventive step if the invention results from the mere discovery of a new form or new property of a known substance which does not result in the enhancement of the known efficacy of that substance, or the mere discovery of any new property or new use for a known substance, or the mere use of a known process unless such known process results in a new product that employs at least one new reactant.

R.A. 8293, as Amended by an Act Providing for Cheaper and Quality Medicines, Amending for the Purpose Republic Act No. 8293 or the Intellectual Property Code, Republic Act No. 6675 or the Generics Act of 1988, and Republic Act No. 5021 or the Pharmacy Law, and for Other Purposes, Rep. Act. 9502, § 26.2 (June 6, 2008) (Phil.), http://www.jpo.go.jp/shiryou_e/s_sonota_e/fips_e/pdf/philippines_e/e_tizai.pdf. Banerjee's brief discussion of the Act is slightly confusing in that it references only the change to Section 22.1. *See* Banerjee, *supra* note 194, at 227.

[198] Section 22.1 now reads as follows:

> [I]n the case of drugs and medicines, the mere discovery of a new form or new property of a known substance which does not result in the enhancement of the known efficacy of that substance, or the mere discovery of any new property or new use for a known substance, or the mere use of a known process unless such known process results in a new product that employs at least one new reactant.

R.A. 8293 § 22.1.

[199] *See* Mukherjeel, *supra* note 180.

[200] Informational Page on Lipitor, DRUGS.COM, https://www.drugs.com/lipitor.html (last visited Nov. 10, 2017).

[201] *See* Matthew Herper, *Why There Will Never Be Another Drug Like Lipitor*, FORBES (Nov. 30, 2011, 9:38 AM), http://www.forbes.com/sites/matthewherper/2011/11/30/why-there-will-never-be-another-drug-like-lipitor/.

[202] Ray Butch Gamboa, *Lipitor v. Avamax*, PHILSTAR GLOBAL (Feb. 27, 2010. 12:00 AM), http://www.philstar.com/business/552870/lipitor-vs-avamax.

Australia, to South Korea, to India, and to the United Kingdom.[203] In 2009, the largest pharmaceutical maker in the Philippines, United Laboratories Inc. (Unilab), launched its own generic version of the drug.[204] Arguing that the initial 1990 patent on atorvastatin had already expired, Unilab petitioned the Philippines Intellectual Property Office (IPO) to also cancel the patent on the salt form of the molecule in July 2009, claiming it was no more than a frivolous invention representing a minor modification that did not pass muster under the country's amended patent code.[205] By August 2009, Unilab was selling its own generic version of Lipitor under the name Avamax.[206] In 2011, Pfizer attained a writ of preliminary injunction against Unilab.[207] The next year, in a surprising turn of events, the same court that issued the earlier injunction reversed course,

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[203] Pfizer unsuccessfully sued Indian generics maker Ranbaxy for infringing its Lipitor patent in Norway in 2007. *See* Allen Andrew Alvarez, *Protecting Intellectual Property Versus Making Essential Medicines Affordable*, 5 ASIAN BIOETHICS REV. 371, 372–73 (2013). Ranbaxy did agree to wait until 2011 to release its generic version. *Id.* In 2008, a South Korean patent court deemed Pfizer's patent on Lipitor invalid. *Id.* On Australia and the U.K., see Michael Sutton, *Lipitor and Atorvastatin: Pfizer Successfully Defends Misuse of Market Power Case*, DIBBSBARKER (Mar. 18, 2015), http://www.mondaq.com/australia/x/381932/Trade+Regulation+Practices/Lipitor+and+atorvastatin+Pfizer+successfully+defends+misuse+of+market+power+case; Kevin Grogan, *Pfizer Settles with Teva over Lipitor in UK*, PHARMATIMES (Oct. 10, 2011), http://www.pharmatimes.com/news/pfizer_settles_with_teva_over_lipitor_in_uk_980269.

[204] Sandeep Kanak Rathod, *Ever-greening: A Status Check in Selected Countries*, 7 J. GENERIC MED. 227, 237–38 (2010). The controversy is detailed further in Rathod's article. *See id.*

[205] *See Philippines Battle Between Pfizer And Unilab Continues*, MIRANDAH: CONNECTING ASIA (Mar. 17, 2010), https://www.mirandah.com/pressroom/item/64-battle-between-pfizer-and-unilab-continues/; Roel Landingin, *Pfizer Takes Aim in Patent Row*, THE FINANCIAL TIMES (Nov. 24, 2009), https://www.ft.com/content/19afde18-d922-11de-b2d5-00144feabdc0?mhq5j=e5; Rathod, *supra* note 204, at 238.

[206] *See Philippines Battle Between Pfizer And Unilab Continues*, *supra* note 205.

[207] InterAksyon, *Cocktales: Justices Reverse Themselves, Allow Unilab To Sell Anti-Cholesterol Generic*, FACEBOOK (Aug. 16, 2012), https://www.facebook.com/InteraksyonTV5/posts/370955042977682.

claiming it had previously overlooked important legal and factual issues.[208]

Given these events, it may not be surprising that Unilab soon after threatened to make another generic version of a different Pfizer blockbuster-drug, Lyrica.[209] Known by its generic name, pregabalin, Lyrica is an anticonvulsant used to treat seizures and epilepsy, for which its maker sought secondary patents based on its use for treating chronic neuropathic pain.[210] It was first approved for various uses in the U.S. and the E.U. in 2004 and was marketed the following year.[211]

Pfizer's squabbles over its Lyrica patents began in 2009 when several Indian companies sought marketing approvals from the FDA for generic versions of the drug.[212] In response, Pfizer pursued legal action in U.S. courts, a strategy that culminated in a June 2014 decision by the U.S. Court of Appeals for the Federal Circuit prohibiting the appearance of generic competitors until 2018.[213] Although Pfizer's victory at the D.C. Circuit came in the face of claims that the patent on pregabalin failed to describe any new invention,[214] the legal situation in the Philippines has acquired a different significance, given the Section 3(d)-style language the country has enshrined in its own IP code.[215] Indeed, from the outset of its public pronouncements threatening to make a generic version

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[208] *Id*.

[209] *See Philippines Battle Between Pfizer And Unilab Continues*, *supra* note 205.

[210] *Lyrica*, DRUGS.COM, https://www.drugs.com/lyrica.html (last updated Nov. 6, 2017).

[211] *Lyrica Approval History*, DRUGS.COM, https://www.drugs.com/history/lyrica.html (last updated Nov. 6, 2017).

[212] *See* N. LALITHA, *Access to Indian Generic Drugs: Emerging Issues*, *in* INTELLECTUAL PROPERTY, PHARMACEUTICALS AND PUBLIC HEALTH: ACCESS TO DRUGS IN DEVELOPING COUNTRIES 225, 236 (Kenneth C. Shadlen et al. eds., 2011).

[213] *See* Susan Decker, *Pfizer Wins Ruling to Block Generic Lyrica Until 2018*, BLOOMBERG (Feb. 6, 2014, 12:12 PM), http://www.bloomberg.com/news/articles/2014-02-06/pfizer-wins-ruling-to-block-generic-lyrica-until-2018. The circuit court upheld the district court's finding of infringement on the patent, particularly on claim 2 of what was called the "819 patent." *Id.*

[214] *Id.*

[215] *See* Banerjee, *supra* note 194.

of Lyrica available in the Philippines, Unilab was hewing closely to that language, claiming that Pfizer's secondary patent was for a method of use, rather than any genuinely new invention resulting in an "enhancement of the known efficacy."[216] Therefore, even notwithstanding the conflicting outcomes of the ongoing legal battle, in the Philippines itself and in the U.S., the controversy will likely reverberate in the years to come.

5. *Argentina (and Beyond)*

Like the Philippines, Argentina has also moved to incorporate Section 3(d)-style provisions into its national IP regime.[217] In May 2012, the country's Ministries of Industry and Health, together with its National Institute for Industrial Property (Argentina's patent office), issued a joint regulation expanding the "Guidelines for Examination of Patentability of Patent Applications concerning Chemical and Pharmaceutical Inventions."[218] The new guidelines set out additional grounds for barring the patentability of a product, including several reasons relating to minor modifications to existing compounds.[219] Polymorphs, like hydrates and solvates, enantiomers, active metabolites, salts, and derivatives of known substances, are thus singled out as non-patentable.[220] As Banerjee observes, the stricture both evokes and exceeds Section 3(d) of the Indian Patents Act since it is meant to deny patentability to such derivatives, even in the event that they can be demonstrated to result in enhanced efficacy, whether therapeutic or otherwise.[221]

As the Argentinian example illustrates, concern over the NCD crisis in the developing world is clearly generating a resurgent questioning of strict approaches to patent rights—and along varied

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[216] *Philippines Battle Between Pfizer and Unilab Continues*, MIRANDAH, (Mar. 17, 2010). https://www.mirandah.com/pressroom/item/64-battle-between-pfizer-and-unilab-continues/.

[217] *See* Joint Resolutions Nos. 118/2012, 546/2012 and 107/2012, May 2, 2012, B.O. (Arg.).

[218] *Id.*

[219] *See* Shouvik Kumar Guha, *Argentina Goes the Section 3(d) Way: Creases of Worry for the Pharmaceutical Patent Applicants?*, SPICY IP (May 23, 2012), http://spicyip.com/2012/05/argentina-goes-3d-way-creases-of-worry.html.

[220] *Id.*

[221] Banerjee, *supra* note 194, at 228.

avenues. Indeed, in Argentina, it is a norm countering the lowering of the bar for patentability that has been instantiated at the level of the ins and outs of patent examination more than in the provisions of the country's IP code. Indeed, it is Argentina's South American counterpart, Brazil, which best exemplifies this observation. Its "prior consent" mechanism[222] thus requires all grants of patents for pharmaceutical products and processes to first be approved by the country's National Sanitary Vigilance Agency (ANVISA).[223] Celebrated and attacked in equal measure as a policy intervention, prior consent has left ANVISA besieged on all sides, both domestically and internationally. Of course, using "policy space" for patent examination is neither new nor specific to NCDs, as Kenneth Shadlen points out.[224] Nevertheless, there is little argument that Argentina's new examination guidelines mirror and reflect the influence of India's newly validated heightened bar for patentability under Section 3(d).

Well beyond the Philippines and Argentina, we find a growing list of countries that have considered or are considering adopting Section 3(d) language, or effectively similar measures, to restrict the patentability of compounds on the grounds of insufficient modifications. Beyond those discussed above, these countries include: Thailand,[225] South Africa,[226] Brazil,[227] Malaysia, Indonesia,

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[222] *See* Law No. 10.196 of Feb. 14, 2001, CÓDIGO DE PROPIEDADE INDUSTRIAL [C.P.I.] (Braz.). The requirement was instituted through an amendment to Article 229 of the 2001 Brazilian Industrial Property Law. *Id.*

[223] *See generally* KENNETH SHADLEN, *The Politics of Pharmaceutical Patent Examination in Brazil*, *in* KNOWLEDGE GOVERNANCE: REASSERTING THE PUBLIC INTEREST 139 (Leonardo Berlamaqui et al. eds., 2012).

[224] *Id*. at 151–57.

[225] *New Patent Examinations Guidelines in Thailand*, IP KOMODO (Sep 13, 2013), http://ipkomododragon.blogspot.com/2013/09/new-patent-examination-guidelines-for.html; *Patent Evergreening in Thailand*, IP KOMODO (Sep. 8, 2011), http://ipkomododragon.blogspot.com/2011/09/patent-evergreening-in-thailand.html.

[226] *See* Julia E. Hill, *Changes to Intellectual Property Policy in South Africa: Putting a Stop to Evergreening?*, 24 EXPERT OPINION THERAPEUTIC PATENTS 839, 843 (2014).

[227] It is often observed that Brazil's approach to IP regime design has been a combination of extremes. *See* CASSANDRA M. SWEET, *The Political Economy of Pharmaceutical Production in Brazil*, *in* THE NEW POLITICAL ECONOMY OF

and China.[228] Ultimately, in the years to come, conflicts over patentability in the context of NCD drugs are likely to only increase.

B. *Compulsory Licensing (of Cancer Drugs)*

Compulsory licensing allows a government or third party to reproduce patented products or processes without the consent of the patent owner.[229] Because governments make such allowances in a variety of ways, compulsory licensing is a term that designates a class of scenarios, rather than a single policy form. With compulsory licensing, government authorization is either more or less explicit and thus results in numerous formal definitions. For example, to some, compulsory licenses are "involuntary contract[s] between a willing buyer and an unwilling seller imposed and enforced by the state."[230] As economists Eric Bond and Kamal Saggi observe, other definitions emphasize the involuntary component and equate compulsory licensing with patent breaking.[231]

Discussion of compulsory licensing has increased significantly with the formation of the WTO and the passage of its underlying Marrakesh and associated agreements. Article 31 of the TRIPS made the practice permissible from the inception of the WTO.[232]

PHARMACEUTICALS 29–47 (Hans Löfgren & Owain David Williams, eds., 2013). Counterpoised with the prior consent mechanism discussed above was an extremely wide definition for what qualifies as an invention. *Id.*

[228] Lisa Kilday, *Global IP Reaction to India's Rejection of the Novartis Drug Patent*, IP WATCHDOG (May 28, 2013), http://www.ipwatchdog.com /2013/05/28/global-ip-reaction-to-indias-rejection-of-the-novartis-drug-patent/id=40778/.

[229] *Compulsory Licensing of Pharmaceuticals and Trips*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (last visited Feb. 11, 2017).

[230] Gianna Julian-Arnold, *International Compulsory Licensing: The Rationales and the Reality*, 33 IDEA: J.L. & TECH. 349, 349 (1993).

[231] Eric W. Bond & Kamal Saggi, *Compulsory Licensing, Price Controls and Access to Patented Foreign Products*, 109 J. DEV. ECON. 217, 218 n. 6 (2014).

[232] TRIPS Agreement, *supra* note 7, at art. 31. In relevant part, it reads:

> [S]uch use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. *This requirement may be waived by a Member in the case of a national emergency or other*

However, its role as a potential policy mechanism became truly visible only as civil society actors and treatment access advocates sought to clarify its meaning.[233] Compulsory licensing was featured prominently at the WTO's 2001 Doha Ministerial meeting as one of the TRIPS-flexibilities under discussion.[234] Indeed, it was the Doha Declaration's demand for clarification on Article 31[235] that started the process leading to the 2005 proposal to amend the TRIPS.[236]

It should be noted that the intensity of efforts to confirm the TRIPS-compliance of compulsory licensing is disproportionately greater than the frequency of its use, especially by developing countries. If anything, the struggle to clarify what the TRIPS permits is as good of an indicator of opposition to compulsory licensing as it is of support.[237] Accordingly, long after the Doha Declaration, developing countries do not have any easy paths toward actually licensing drugs. India, often painted as one of the worst abusers of the practice, received its first application for a compulsory license

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> *circumstances of extreme urgency or in cases of public non-commercial use*. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly.

Id. (emphasis added).

[233] In the United States especially, among the leading organizations working on the issue has been Knowledge Ecology International. For its work on compulsory licensing, see *Compulsory licenses*, KNOWLEDGE ECOLOGY INT'L, https://www.keionline.org/cl (last visited Nov. 10, 2017).

[234] MOHAMMAD TOWHIDUL ISLAM, TRIPS AGREEMENT OF THE WTO: IMPLICATIONS AND CHALLENGES FOR BANGLADESH 266 (2013).

[235] On the limits of Article 31, see Mike Gumbel, *Is Article 31 Big Enough? The Need to Promote Economies of Scale in the International Compulsory Licensing System*, 22 TEMP. INT'L & COMP. L.J. 161 (2008).

[236] *See* Jerome Reichman, *Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, 37 J.L. MED. ETHICS 247 (2009) (describing how compulsory licensing survived the initial TRIPS negotiations).

[237] *See id.* at 261. Opposition also continues outside of WTO channels. *See* Ed Silverman, *Pharma Narrowly Defines When Compulsory Licenses Should Be Used*, WALL ST. J.: PHARMALOT (Feb. 24, 2015, 1:23 PM), http://blogs.wsj.com/pharmalot/2015/02/24/pharma-narrowly-defines-when-compulsory-licenses-should-be-used/.

in 2011. To date, that application for the drug Nexavar is the only compulsory license the country has ever issued in the post-TRIPS era.[238] This can be compared with more than 1,000 pharmaceutical patent approvals the country granted from 2007 to 2010 alone.[239]

Recent studies confirm this general observation. According to one analysis, since 1995, there have been only 24 "verified" episodes in which "a [compulsory license] was publicly entertained or announced by a WTO member state."[240] Of the 24 verified episodes, nearly half occurred between 2003 and 2005, during the small window that opened in the immediate aftermath of the Doha Declaration.[241] Only 13 of the verified episodes resulted in the issuance of licenses that were actually compulsory; three others resulted in voluntary agreements to license in the wake of negotiations, and of the remaining eight, the majority lead to nothing more than a price discount.[242] Furthermore, the total number of "potential," rather than "verified," episodes the researchers found summed to only 34.[243]

What countries were involved in the 24 verified episodes? Thirteen cases concerned upper-middle income countries, and another three cases concerned high-income countries.[244] Low-income (including "least developed") countries were almost entirely absent.[245] Finally, the large majority of verified episodes involved licensing or price discounting of drugs for treating HIV/AIDS.[246] Of course, HIV/AIDS is a unique ailment due to both its visibility and

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[238] Sai Vinod, *Why Aren't There Any Takers for Compulsory Licenses?*, SPICY IP (Feb. 12, 2013), http://spicyip.com/2013/02/why-arent-there-any-takers-for.html.

[239] *Id*.

[240] Reed Beall & Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, 9 PLOS MED. 1, 1 (2012).

[241] *Id.* (explaining that 11 of 24 were episodes occurred within a two-year period).

[242] *Id.* at 9.

[243] *Id.* at 3.

[244] *Id.* at 4.

[245] *Id.* at 4.

[246] *Id.* (explaining that 16 of 24 episodes involved drugs for treating HIV/AIDS).

the way it explicitly figured into the campaigns for treatment access that led to the Doha Declaration in the first place.[247]

Thus, despite what many may assume, compulsory licensing by developing countries is rare and difficult. Nevertheless, each next potential case is easily a magnet for recrimination. Consequently, developing countries face a standing risk even when entertaining these licenses, let alone if they try to issue actual licenses. Indeed, when attempts have been made, powerful countries have been quick to communicate that their discontent may be made manifest through the WTO's remediation system, a playing field that many suggest is not level.[248]

These circumstances call for an evaluation of compulsory licensing from both a qualitative and a quantitative approach. Even though there are too few instances of such licensing to provide a strong statistical trend over time, individual examples still reveal important information about how battle lines have been drawn and redrawn.

1. *The Thai Prelude to Recent Events*

Recently, the international community marked an important moment in the compulsory licensing saga, making for a culmination of sorts in the fight against HIV/AIDS. This took place in 2007, when Thailand and Brazil sanctioned licenses for two on-patent HIV/AIDS drugs, Abbott/Abvie's Kaletra and Merck's Efavirenz, within less than six months of one another.[249] Concomitant with its Kaletra and Efavirenz decisions, Thailand led the way toward pushing the battle over compulsory licensing into the field of NCD therapies as well. In January of 2007, the country's Health Ministry authorized a generic version of clopidogrel bisulfate, an anti-platelet medicine used to fight heart disease that is jointly marketed by Bristol-Myers Squibb and the French

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[247] *Id.* at 1.

[248] *See, e.g.*, ETHAN KAPSTEIN, ECONOMIC JUSTICE IN AN UNFAIR WORLD: TOWARD A LEVEL PLAYING FIELD (2006); Surya Subedi, *The Notion of Free Trade and the First Ten Years of the World Trade Organization: How Level is the 'Level Playing Field'?*, 53 NETH. INT'L L. REV. 273 (2006).

[249] Thailand licensed Kaletra in January 2007 and Brazil licensed Efavirenz in May. *See* Bond & Saggi, *supra* note 231, at 218.

multinational Sanofi-Aventis under the brand name Plavix.[250] In 2008, the Health Ministry then upped the ante by adding several anti-cancer medications to its list, including Gleevec, docetaxel, erlotinib, and femara.[251] The Gleevec case resulted in a price discount, rather than a license,[252] while the other three cases are ongoing.

Not surprisingly, a vigorous pushback against Thailand set in. Opponents in the industry and the USTR alleged that the country failed to follow proper procedures by neglecting to negotiate with the patent holders first.[253] For its part, Thailand contended that prior negotiation was only necessary in the case of licenses for commercial use under Section 51 of the country's Patent Act.[254] Its own Health Ministry, Thailand argued, was issuing licenses only for public use,[255] which required notification from the Department of Disease Control alone.[256] Notwithstanding Thailand's defense of its action, the controversy still stifled the momentum of the Health Ministry's actions. To date, none of the licenses for NCD drugs that the country made notifications for in the period from 2007 to 2008 pursuant to Section 51—whether for Plavix or any of the three anti-cancer medicines—have been fully executed. In fact, even for its two HIV/AIDS drugs, only the license for Efavirenz has been fully executed; the license for Kaletra has not been.[257]

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[250] *Plavix*, DRUGS.COM, https://www.drugs.com/plavix.html (last visited Nov. 10, 2017).

[251] *See* Siraprapha Khim Rungpry, *Compulsory Licensing Issues and Trends in Asia*, 2 PHARM. PAT. ANALYST 681, 682 (2013).

[252] S. Tunsarawuth, *Thailand Avoids Compulsory License on Cancer Drug; 3 More Drugs Undecided*, IP WATCH (Jan. 31, 2008), http://www.ip-watch.org/2008/01/31/thailand-avoids-compulsory-licence-on-cancer-drug-3-more-drugs-undecided/.

[253] Mishka Glaser & Anne Marie Murphy, *Patients versus Patents: Thailand and the Politics of Access to Pharmaceutical Products*, 27 J. THIRD WORLD STUD. 215, 221–24 (2010).

[254] *Id.* at 222–24.

[255] Patent Act, B.E. 2522 § 51 (1979) (Thail.).

[256] Glaser & Murphy, *Patients versus Patents*, *supra* note 256, at 223–24.

[257] Sakda Thanitcul & Matthew Lim Braslow, *Compulsory Licensing of Chronic Disease Pharmaceuticals in Thailand*, 37 J. PHARM. SCI. 61, 66 (2013).

Thailand's attempt to push its battles into the NCD context is best regarded as a precursor to a more insistent effort to reorient compulsory licensing policies that has been afoot for more than five years. An example of a more urgent situation is India's licensing of the cancer drug Nexavar in 2012. The Nexavar decision reopened not one, but two different conversations about compulsory licensing in the NCD crisis. One conversation broached the issue of licensing on the grounds of non-commercial use that has been at the heart of the efforts by Thailand. The other conversation broached licensing on the grounds of a so-called failure to work a patent locally.[258] The latter conversation has been largely dormant since 2001, when the U.S. was forced to withdraw a WTO suit against Brazil for AIDS/HIV treatment that involved failure to work issues. With the Nexavar controversy pushing the question into the NCD context, however, matters changed considerably.

2. *India and Nexavar*

As for the controversies that have erupted in cases of patent denial, India has been at the center of those involving the compulsory licensing of NCD drugs as well. For much the same reason, India also demonstrates the vulnerability of any emerging consensus in favor of reframing the access-incentivization polarity around NCDs.

As the controversy over Gleevec was unfolding, India found itself at the center of another storm involving the very first compulsory license the country approved on a patented product/process in the post-TRIPS era. As in the Gleevec case, the Nexavar case involved a prominent cancer drug, although the

[258] Failure to work is a technical doctrine that has traditionally meant the failure to work a patent industrially, as in by manufacturing the given patented product or by failing to apply in some relevant industrial application the given patented process. 'Working a patent' locally means the failure to manufacture/apply the patent locally. In the TRIPS context the question of whether a patent can be "worked" "locally" has crystallized around whether such a requirement can be satisfied by mere import of a patented drug or whether actual local manufacturing is required. *See* NUNO PIRES DE CARVALHO, THE TRIPS REGIME OF PATENT RIGHTS, 283-93 (2010).

German multinational Bayer held the rights.[259] Known under its chemical name as sorafenib, Nexavar is another tyrosine kinase inhibitor used as a targeted therapy in the treatment of certain kidney, liver, and thyroid cancers.[260] Sorafenib was developed by Bayer in conjunction with the San Francisco-based Onyx Pharmaceuticals and was approved for use by the FDA in 2005 and the E.U. in 2006.[261] Nexavar is the tosylate salt version of sorafenib.[262]

The origins of the *Nexavar* controversy date back to 2001 when Bayer applied for patent protection in India. It received protection in 2008.[263] Cipla, a generics manufacturer, then requested approval to launch a generic version of the medicine, and Bayer's initial attempt to squash Cipla's request was denied by the Delhi High Court.[264] An exorbitantly expensive drug, Nexavar was sold only in small quantities in 2009 and 2010.[265] Once the drug initially became available, Cipla announced that it would actually launch its generic version under the name Soranib in February 2010.[266] A month later, in March 2010, Bayer returned to the Delhi High Court and sued Cipla for patent infringement.[267] In response, Cipla challenged the validity of Bayer's patent and countersued for its revocation.[268] The Cipla trial commenced before the Delhi High Court on March 23, 2011.[269] The entire case, however, was overtaken by other events, with Natco, another Indian generic manufacturer, filing a

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[259] *Sorafenib (Nexavar)*, DRUG APPROVALS AND DATABASES, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2005/021923_s000_NexavarTOC.cfm (last visited Nov. 11, 2017).

[260] *Id.*

[261] *Id.*

[262] *Id.*

[263] Bayer Corp. v. Union of India, WP(C) No.7833/2008 (Del. H.C. Aug. 18, 2009) (India).

[264] *Id.*

[265] Enrico Bonadio, *Compulsory Licensing of Patents: The Bayer/Natco Case*, 10 EUR. INTELL. PROP. J. 719, 720 (2012).

[266] *Id.*

[267] *See* Prashant Reddy, *Taking a Closer Look at the Nexavar Litigation*, SPICY IP (Sep. 29, 2011), http://spicyip.com/2011/09/guest-post-taking-closer-look-at.html.

[268] *Id.*

[269] *Id.*

compulsory licensing application on Nexavar only four months later in the summer of 2011.[270] The Controller General of Patents, Designs & Trademarks approved Natco's application six months later on March 9, 2012.[271]

Key to both Natco's application and the Controller General's approval was the scarcity of sorafenib on the Indian market. The Controller General thus found that Bayer had made no effort to manufacture the drug locally or to import it.[272] In light of its claim that Bayer had failed to "locally work" its patent in India under Section 84(1)(c) of the Patents Act,[273] Natco proposed that if it was granted a compulsory license it would make its generic version of sorafenib available for Rs.8,800/month (as compared to Rs.280,428/month for branded Nexavar and Rs.30,000/month for Cipla's Soranib).[274] While under the terms of the license Natco was required to pay a six percent royalty, Bayer still appealed the Controller General's decision to the IPAB but was met with defeat on March 4, 2013.[275] Although Bayer continued to press its challenge against the Natco license—both to the Bombay High Court[276] and Indian Supreme Court[277]—it was unsuccessful.

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[270] Khomba Singh, *Natco Pharma Files India's First Compulsory Licence Plea*, THE ECONOMIC TIMES (Aug. 2, 2011, 5:15 AM IST), http://articles.economictimes.indiatimes.com/2011-08-02/news/29842834_1_compulsory-licence-sorafenib-tosylate-natco-pharma.

[271] In the Matter of Natco Pharma Limited and Bayer Corporation, Order Compulsory License App. No. 1 of 2011 (Controller of Patents, Mumbai, March 9, 2011) (India). http://www.ipab.tn.nic.in/045-2013.htm.

[272] *Id.*

[273] In India, applications for compulsory licenses can be filed any time after three years from the date of the grant of a patent provided that "the patented invention is not worked in the territory of India." The Patents Act (India), No. 39 of 1970, § 84(1)(c), INDIA CODE (1970).

[274] *In the Matter of Natco Pharma Limited*, *supra* note 271, at 15.

[275] Bayer v. Union of India & Natco, OA/35/2012/PT/MUM (Intellectual Property Appellate Board, Chennai, March 4, 2013) (India), http://www.ipabindia.in/pdfs/order-45-2013.pdf.

[276] Writ Petition, Bayer Corp. v. Union of India & Others, No. 1323/2013 (Bombay H.C. July 15, 2014) (India).

[277] The Supreme Court dismissed Bayer's appeal, which it sought through special leave. Petition for Special Leave to Appeal, Bayer Corp. v. Union of India & Others, (C) No. 30145/2014 (SC Dec. 12, 2014) (India).

Both the Controller General and the IPAB (partly) based their decisions against Bayer on Section 84(1)(b)[278] of the Patents Act, finding the company failed to make sorafenib "available to the public at a reasonably affordable price."[279] More controversially, they also weighed in on the nature of India's "local working" requirement under Section 84(1)(c).[280] Indeed, from the very inception of the WTO, there was confusion about the status of such provisions under the TRIPS. Article 27.1's seeming negation of local working requirements,[281] for example, contradicts Article 31's seeming allowance of them.[282] It is no wonder that such contradictions soon reached the WTO's Dispute Settlement Body (DSB), most importantly with the U.S. suit against Brazil in 2001.[283] That case revolved around a local working requirement Brazil had included in the new industrial property law it had enacted in order to bring itself into TRIPS-compliance.[284]

Given its indeterminate outcome, the U.S.-Brazil case ushered in nearly fifteen years of uncertainty around local working requirements under the TRIPS agreement. Of course, as in many other areas of IP regime design, the states that had been most central to the WTO's creation continued to construe local working through the lens of the TRIPS as a mechanism for eliminating "protectionism."[285] Any robust version of local working was thus portrayed as antithetical to the spirit of liberalization, a stance that stymied the emergence of any clear definition of what it meant to

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[278] The Patents Act (India), § 84(1)(b).

[279] *Id.* § 84(1)(c).

[280] *See id.*

[281] *See* Panel Report, *Patent Protection of Pharmaceutical Products*, WTO Doc. WT/DS114/R (Mar. 17, 2000) (Can.). For contrary views in academic literature, see, for example, Bryan Mercurio & Mitali Tyagi, *Treaty Interpretation in WTO Dispute Settlement: The Outstanding Question of the Legality of Local Working Requirements*, 19 MINN. J. INT'L L. 275 (2010).

[282] TRIPS Agreement, *supra* note 7, at art. 31.

[283] *See* Paul Champ & Amir Attaran, *Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the U.S.-Brazil Patent Dispute*, 27 YALE J. INT'L L. 365, 380–83 (2002).

[284] *Id.* The United States was eventually forced to withdraw the case in the face of public scrutiny. *Id* at 381.

[285] *See id.* at 380.

"work" a patent.[286] In the wake of the U.S.-Brazil case, therefore, confusion remained around whether local working requirements were among the TRIPS' oft-proclaimed flexibilities.[287]

Continuing on this long interim of indeterminacy, the Nexavar controversy in its own right should be seen as a landmark controversy, much like the Gleevec case. Centering on a cancer drug, it is a clear departure from the unresolved 2001 dispute between the U.S. and Brazil about local working in the context of AIDS/HIV treatments.[288] Equally notable is that the Controller General and the IPAB in India addressed the local working issue in distinct ways. According to the Controller General, to work the patent in India required that Nexavar had to be domestically manufactured, especially given Bayer's existing facilities and operations in the country.[289] The Controller General thus rejected Bayer's claim that its nominal imports of Nexavar into India met this requirement.[290] In the Controller's own words, local working means "manufactured to a reasonable extent in India."[291]

The IPAB, on the other hand, ruled out deciding *a priori* that working "totally excludes import, or that 'working' is synonymous to 'import' and that if there is no manufacture in India, then there is no working."[292] Instead, it held that a case-by-case approach to the meaning of the requirement was needed, with it ultimately being the patentee's responsibility to "show why [the patented product] could

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[286] *Id.*

[287] For a detailed negotiation history of TRIPS, see *id.* at 373–79.

[288] *See id*. at 380–83. The United States withdrew the case once word began to spread as AIDS/HIV activists continued pursuing Al Gore in the wake of his failed 2000 presidential bid. Brazil had perhaps the world's leading government-run public health intervention for tackling AIDS/HIV by making anti-retrovirals available to its population. It was in response to the DSB case that Brazil, itself, made its earliest intimations that it was considering issuing a compulsory license on Efavirenz. *Id.*

[289] In the Matter of Natco Pharma Limited and Bayer Corporation, Order Compulsory License App. No. 1 of 2011, at 44–45 (Controller of Patents, Mumbai, March 9, 2011) (India). http://www.ipab.tn.nic.in/045-2013.htm.

[290] *Id.*

[291] *Id*. at 45 (internal quotations omitted).

[292] Bayer v. Union of India & Natco, OA/35/2012/PT/MUM, at para. 52 (Intellectual Property Appellate Board, Chennai, March 4, 2013) (India), http://www.ipabindia.in/pdfs/order-45-2013.pdf.

not be locally manufactured."[293] The IPAB was eager to note that like the Controller, it was of the "of the opinion that the word 'worked' has a flexible meaning;" moreover, it would be insensible to allow the local working requirement to be "satisfied by having import monopoly for all patented inventions."[294] Ultimately, therefore, the IPAB's decision functioned to secure the local working as a basis for compulsory licensing under Section 84 of the Patents Act.[295]

At the same time, the validation of the Nexavar compulsory license in India was more than just an endorsement of a traditional TRIPS flexibility. Indeed, more importantly, it opened a new front in the long-standing battle over national patent regime design in an age of pushing for the upward harmonization of IPR standards through free trade agreements.[296] With so many on-patent drugs reaching India through import,[297] a blanket prohibition against equating import with local working would probably not have withstood political pressure. The way in which the Controller General and IPAB's decisions both broached and stopped short of prohibiting any such equivalence between import and local working, therefore, must be appreciated as the complex strategic maneuver it effectively comprised.

3. *India and Possible Compulsory Licenses for Other Cancer Drugs*

A dramatic series of events followed after the licensing of Nexavar. In January 2013 the Indian Government's Union Health Ministry proposed to the Department of Industrial Property and Promotion (DIPP) that the Government should proceed to license three other cancer drugs.[298] On the list were the biologic

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[293] *Id.*

[294] *Id*. at para. 52.

[295] *See id.*

[296] *Id*. at para. 41.

[297] Shamnad Basheer & Mrinalini Kochupillai, The 'Compulsory Licence' Regime in India: Past, Present and Future (July 1, 2005) (unpublished article), https://ssrn.com/abstract=1685129.

[298] P.K. Pradhan, *Health Ministry Recommends Compulsory Licensing of Three Anti-cancer Drugs*, LIVEMINT (Jan. 16, 2013), http://www.livemint.com

trastuzumab, marketed under the name Herceptin by the Roche Pharmaceuticals-owned Genentech,[299] Bristol-Myers Squibb's ixabepilone, a tubule binding multi-drug resistant chemotherapeutic agent, and the tyrosine kinase inhibitor dasatinib, another Bristol-Myers Squibb drug, which is used to fight chronic myeloid leukemia and marketed under the name Sprycel.[300] Not surprisingly, the announcement further increased the torrent of recrimination by the pharmaceutical industry and accelerated efforts by the U.S. to reverse India's course.[301] Thus far, none of these cancer drugs has laid the basis for India in issuing its second-ever compulsory license. Indeed, significant legal blows were dealt to the cases of trastuzumab/Herceptin and dasatinib/Sprycel very quickly; in the case of trastuzumab, the DIPP even went so far as to declare that it would be ignoring its counterpart agency's plea.[302]

Even so, the controversy did not simply end. In August 2013, Roche unexpectedly announced it would not attempt to renew its Indian Herceptin patent.[303] The company then promptly brought suit against the India's Biocon along with the U.S. generic maker, Mylan, after the duo obtained regulatory approval to sell a jointly developed "biosimilar"[304] version of trastuzumab on the Indian

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/Companies/F3Rn5jCkKjCJNYzhtuQseO/Health-ministry-recommends-compulsory-licensing-of-three-ant.html.

[299] *See id.*

[300] Patralekha Chatterjee, *2013: India Battles for Right to Use Compulsory Licenses to Make Medicines Affordable*, INTELL. PROP. WATCH (Jan. 22, 2013), http://www.ip-watch.org/2013/01/22/2013-india-battles-for-right-to-use-compulsory-licences-to-make-medicines-affordable.

[301] Gardiner Harris, *India's Efforts to Aid Poor Worry Drug Makers*, N.Y. TIMES (Dec. 29, 2013), http://www.nytimes.com/2013/12/30/health/indias-efforts-to-aid-poor-worry-drugmakers.html.

[302] Sidhartha, *Health Ministry Ups the Ante Against Patents*, TIMES OF INDIA (Jul. 23, 2013), http://timesofindia.indiatimes.com/business/india-business/Health-ministry-ups-ante-against-patents/articleshow/21262080.cms.

[303] P.T. Jyothi Datta, *Roche Not to Pursue Patent on Breast Cancer Drug Herceptin*, HINDU BUS. LINE (Aug. 15, 2013), http://www.thehindubusinessline.com/companies/roche-not-to-pursue-patent-on-breast-cancer-drug-herceptin/article5026258.ece.

[304] Biosimilars are follow-up versions of biologics that are developed after patent protection on the original drug ends. Given their greater molecular complexity, biosimilars are generally less exact copies of the original than is the

market.[305] Although the Delhi High Court blocked Mylan and Biocon from launching their generic Herceptin competitor in February 2014, other loose ends of the controversy persisted.[306]

In February 2013, the Indian company BDR Pharmaceuticals submitted to the Mumbai-patent office the second ever application for a compulsory license in India during the post-TRIPS era, this time for dasatinib/Sprycel.[307] BDR proposed to sell its generic competitor for Rs.8,000 (or US$130) for a month's treatment as compared to the Rs.160,000 (or US$2,600) that Bristol-Myers Squibb charges.[308] Once more official action created a roadblock in October 2013, when the Controller General of the IPO rejected the licensing application on technical grounds, refusing to consider its merits because of BDR's failure to make out a *prima facie* case.[309]

Exactly how to interpret this rather dizzying series of events is a complicated matter. On the one hand, the clear setbacks to the licensing of both Herceptin and Sprycel may indicate that the Nexavar decision will, in the long term, have less practical significance than it first seemed. Yet while political reality may be

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case for older versions of traditional small molecule drugs. As a result, a great deal of controversy surrounds biosimilar patent approval by health authorities and IPR issues. *See* Ganesan Marimuthu et al., *Maintaining Patents Protecting Biologics or Small-Molecule Drugs*, 30 NATURE BIOTECH. 50 (2012); Vincent J. Roth, *Will FDA Data Exclusivity Make Biologic Patents Passé*, 29 SANTA CLARA COMPUT. & HIGH TECH. L.J. 249 (2012–2013).

[305] Soma Das, *Roche Sues Biocon, Mylan, DCGI Over Breast Cancer Drug*, ECON. TIMES (Feb. 7, 2014), http://articles.economictimes.indiatimes.com/2014-02-07/news/47126682_1_trastuzumab-breast-cancer-drug-herceptin.

[306] *Id.* The High Court's order can be found online at http://indiankanoon.org/doc/62291003.

[307] Rupali Mukherjee, *Interesting Turn in Dasatinib Patent War*, THE TIMES OF INDIA (Sep. 12, 2013), https://timesofindia.indiatimes.com/city/mumbai/Interesting-turn-in-Dasatinib-patent-war/articleshow/22509728.cms.

[308] *Id.*

[309] For a more extensive account of the decision see Harsha Rohatgi, *Indian Patent Office Rejects Compulsory Licensing Application*, IIPR (Nov. 13, 2013), http://www.iiprd.com/indian-patent-office-rejects-compulsory-licensing-application-bdr-pharmaceuticals-pvt-ltd-vs-bristol-myers-squibb/; C.H. Unnikrishnan, *BDR Pharma's Compulsory Licensing Application for Blood Cancer Drug Rejected*, LIVEMINT (Oct. 31, 2013), http://www.livemint.com/Companies/lR6TQA2EY5gejvMl63zHOM/Patent-office-rejects-BDR-Pharmas-application-for-blood-can.html.

pushing in such a direction, it is still misleading to make too much of this development.[310] Indeed, even in the case of Herceptin and Sprycel, there was no simple reversal of the larger implications of the Nexavar decision. Already from January 2013, when India's Health Ministry began urging the DIPP to issue licenses for trastuzumab, ixabepilone, and dasatinib, the basis it proposed for doing so had nothing to do with Section 84 of the Patents Act or its local working provision. Rather, the proposal was for the DIPP to invoke the "national emergency" basis for compulsory licensing under Section 92.[311] In contrast to Section 84, Section 92 does not require the costly litigation step of filing a plea; instead, under Section 92 compulsory licenses can be issued directly upon notice from the central government for "national emergency, urgency, or public non-commercial use."[312]

Whatever the final fate of Herceptin and Sprycel may be, it does not necessarily limit the significance of the Nexavar decision. Even the failed attempt by BDR Pharmaceuticals to secure a license on Herceptin (which was pursued via the Section 84 route) was not rejected on its merits but only on the threshold issue of pleading.[313] Moreover, with the Delhi High Court's decision, the battle over Herceptin has, in a sense, simply reverted back to Section 92. Indeed, the negative judicial outcome on the Section 84 application reinvigorated the Union Health Ministry's calls to issue a direct government license and a growing rift with the DIPP.[314] Of course, there is no guarantee that the Health Ministry's position will win out—all the less, in fact, given that the DIPP, which is charged with taking final action, has clearly grown more rather than less hostile to invoking Section 92.[315]

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[310] For more on the intense pressure brought to bear on India for the Sprycel and Dasatinib cases, see Deborah Cohen, *US Trade Rep Is Pressing Indian Government to Forbid Production of Generic Cancer Drug, Consortium Says*, 314 BMJ 6593 (Nov. 4, 2014), http://dx.doi.org/10.1136/bmj.g6593.

[311] The Patents Act (India), No. 39 of 1970, § 92(3), INDIA CODE (1970).

[312] *Id.*

[313] Rohatgi, *supra* note 309.

[314] *See* Arun S., *DIPP Prescribes a Dose of Caution on Compulsory Licenses*, FIN. EXPRESS (Dec. 4, 2014), http://www.financialexpress.com/industry/dipp-prescribes-a-dose-of-caution-on-compulsory-licences/15478/.

[315] *See id.*

Regardless, these events have reopened another crucial debate, as onlookers have been left to behold a major developing country potentially invoking the national emergency/extreme urgency/public non-commercial use basis[316] of licensing. That another potential TRIPS-flexibility that had been dormant for years should come back to life in the context of cancer/NCD drugs makes recent events in India unprecedented.[317] Therefore, even if the radical challenge of national emergency-based compulsory licensing does not come to fruition,[318] the ongoing controversy around Section 92 is likely to shore up the nascent jurisprudence of Section 84's "local working" that may have its own potential radical consequences. Indeed, the more that old battle lines are redrawn in the context of NCD drugs, the less likely it becomes that conflicts transpiring within those lines will easily be contained. There is, in other words, only so much of their reputational capital that pharmaceutical multinationals can spend in opposition, especially within any single country and especially as it becomes more apparent that the economics of the access-incentivization debate applies very differently to drugs for NCDs as compared to their counterparts for infectious diseases.

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[316] *See* Bayer v. Union of India & Natco, OA/35/2012/PT/MUM (Intellectual Property Appellate Board, Chennai, March 4, 2013) (India), http://www.ipabindia.in/pdfs/order-45-2013.pdf.

[317] Licenses for failure to work and "national emergency" have rarely been used. This is why the language of Article 31(b) had to be reconfirmed in the Doha Declaration. *See* Doha Declaration, *supra* note 51.

[318] The issue of under what circumstances a national emergency would have to be declared as the basis for a license is complicated and easy to misconstrue, including, because it is not a basis that has been made much use of. As WTO explains:

> For "national emergencies", "other circumstances of extreme urgency" or "public non-commercial use" (or "government use") or anti-competitive practices, there is no need to try first for a voluntary license. It's the only instance when the TRIPS Agreement specifically links emergencies to compulsory licensing: the purpose is to say that the first step of negotiating a voluntary license can be bypassed in order to save time. But the patent owner still has to be paid.

Compulsory Licensing of Pharmaceuticals and TRIPS, WTO INFO. AND MEDIA REL. DIV. (Sept. 2006), https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm.

4. *Ecuador and Licenses for Cancer, Arthritis, and Other Drugs*

Alongside Brazil, Ecuador has been the other Latin American country taking the lead in compulsory licensing. While many counterparts in Latin America allow for the practice, to date only these two countries have actually issued licenses.[319] The legal basis for Ecuadorian licensing is grounded in Article 363(7) of the country's constitution—obligating the state to guarantee availability and access to quality medicines.[320] Further provision is also made through Presidential Decree 118 from 2009, which allows licenses to be "granted at any time for reasons of public interest, emergency, or national security."[321] Under Ecuador's rule regime, requests for compulsory licenses must first be submitted to the country's Institute of Intellectual Property (IEPI), with successful licensor's then (possibly) obliged to pay a royalty to the patent holder.[322] Under this procedure, the IEPI made its first licensing decisions—for AIDS/HIV drugs—in 2010, with a second round completed for additional anti-retrovirals in 2012.[323] By the end of 2014, the IEPI had considered or was considering some 32 other applications, with nine licenses in total having been issued by that point.[324] Among the applications were a high number for NCD drugs, including etoricoxib, Merck's anti-inflammatory compound for arthritis branded under Arcoxia, Nucoxia, and Vargis; Novartis' Myfortic, the sodium salt of mycophenolic acid, an immunosuppressant used in post-transplant patients; Pfizer's sunitinib, a tyrosine kinase inhibitor used to treat several cancers marketed under as Sutent; and certolizumab, a monoclonal antibody used in the treatment of

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[319] Carlos Correa, COMPULSORY LICENSING: PRACTICAL EXPERIENCES AND WAYS FORWARD 51 (Reto M. Hilty & Kung-Chung Liu eds., 2014).

[320] *Id.* at 53.

[321] *Id.* at 53. For the full text of the executive order, see Decreto Presidencial, No. 118 (Oct. 23, 2009) (Ecuador).

[322] Correa, *supra* note 319, at 54.

[323] *Id.* at 53–55.

[324] Maria Augusta Alvarez Moreno, *Guest Post: Nine Mandatory Licenses Allow Greater Access to Medicines in Ecuador*, INTELL. PROP. WATCH (Dec. 9, 2014), http://www.ip-watch.org/2014/09/12/guest-post-nine-mandatory-licenses-allow-greater-access-to-medicines-in-ecuador/.

Crohn's disease and rheumatoid arthritis, which Belgium's UCB markets under the name Cimzia.[325]

Ecuador's history of licensing since 2009 is noteworthy, not simply because it demonstrates a steady advance beyond HIV/AIDS drugs or even because the country has been able to avoid recrimination in a way not all of its counterparts have. The country's actions also stand out because of the diversity of the NCD drugs it has moved to make available. The certolizumab case, similar to Herceptin in India, is of interest as it supports licensing in the new area of biologics.[326] In this respect, Ecuador has taken the lead in questioning the norm of strict patent rights via licensing efforts beyond infectious disease drugs.

VII. CONCLUSION

Part VI focused only on controversies involving two mechanisms by which developing countries have been shifting their efforts to contest the norm of strict patent rights in the context of therapies for NCDs. However, there are other mechanisms that developing countries are considering besides simply heightening the bar for patenting modifications and compulsory licensing. In India, for example, there has been renewed discussion around a twenty-first-century version of price ceilings on pharmaceuticals. Other governments, like those in China and South Africa, continue to consider ways to revise their patent codes. In still other countries, the high price of cancer medicines has led to the possibility of outright patent revocation.

At the same time, it is not only on the grounds of these shifting facts that we must now ask whether counter-harmonizing away from drug patents may emerge as a new norm rather than just a series of exceptions proving strict IPR the rule. Rather, this Article has also sought to show how these shifting facts make the ostensibly pure theoretical dilemma between the norms of access and incentivization seem less compelling than it has otherwise been

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[325] *Id.*

[326] *See* In the Matter of Natco Pharma Limited and Bayer Corporation, Order Compulsory License App. No. 1 of 2011 (Controller of Patents, Mumbai, March 9, 2011) (India). http://www.ipab.tn.nic.in/045-2013.htm.

made to seem. Of course, this is not to say that the Article has denied there is any tension between access and incentivization—at least at some sufficiently high level of abstraction and provided that drug patents remain a cornerstone of our innovation system.

However, by implicitly envisioning access solely in terms of the availability to the world's poor of treatments for conditions that only or primarily afflict them, we have allowed an otherwise remote possibility—of multinationals becoming altogether unable to deliver therapies to the market—seem as if it is acute. As with ostensibly context-free normative reasoning in general, the access-incentivization dilemma has thus carried an inherent tendency to facilitate status quo arrangements and directions of movement in law and policy making.

Indeed, it is because of this reason that this Article has eschewed simply taking a traditional path of a normative argument for or against drug patents. By highlighting how the legal and administrative conflict in the developing world has tracked the changing face of its public health crisis more closely than existing discussion in the developed world, it instead urges decision makers to capitalize on the dramatic natural experiment now unfolding before our eyes. It is thus crucial to see that there has never been a better way to gauge whether departing from a regime of strict IPR will really push us to the brink of a world without medicines. Indeed, as the one example of infectious disease drugs that are close in their economics to those for NCDs has already shown, harmonizing away from strict patent rights has hardly prevented new forms of HIV/AIDS combination therapy from materializing. In fact, they have actually proliferated—much to the benefit of individuals in *both* the developing and developed world.

In the final analysis, therefore, this Article's plea is for policy makers to ensure that the natural experiment that the NCD crisis has created comes to fruition. In so doing, decision makers will be encouraging solutions that add to or even improve upon the best existing proposals for solving the ongoing drugs-for-the-developing world dilemma as it advances into its second generation of visibility. This is because existing proposals have tended to focus on actions by international institutions subject to a great deal of internal inertia

and political pressure from the major power holders within the international system than developing countries themselves face. Given the focus of these proposals, moreover, they also have the downside of tending to leave the supposed normative intractability of the access-incentivization dilemma intact.

In contrast, the solutions this Article tracks are not only practical but also possibly more forceful insofar as they originate from initiatives that are already being implemented by ground level actors in the developing world. This Article has argued that it is those actors who have led the way in addressing the public health crises their countries face to reconsider the true ethical and economic burdens that remain if pharmaceutical patenting is the default.

Of course, it may only be a coincidence that the shifting context of legal and administrative conflict in low and middle-income countries has ended up dovetailing with the unexpected popular support in high-income countries for renegotiating the terms of free trade liberalization. Yet, even so, law and policy makers would be remiss if they fail to see the great opportunity that exists within the seeming crisis the world order is now going through. As we garner better evidence about the consequences of deviating from strict IPR in the NCD drug context, we will only end up better positioned to rewrite the rules of our global innovation system in a way that makes sense for a twenty-first century that has moved well past its post-Cold War antecedents.

Finally, although this Article has focused on the policy-making opportunity that lies ahead to benefit the inhabitants of the developing world, its implications obviously do not end there. For decision makers here in the United States, it is vital to seize the opportunity that is now emerging to adjust the legal regime that governs pharmaceutical innovation and availability. Otherwise, inhabitants of the developed world will also be left, like their counterparts in the developing world, to face the seemingly limitless costs of NCDs.